

Increasing boys' and girls' intentions to avoid teenage pregnancy: a cluster randomised controlled feasibility trial of an interactive video drama-based intervention in post-primary schools in Northern Ireland

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Abstract

Increasing boys' and girls' intentions to avoid teenage pregnancy: a cluster randomised controlled feasibility trial of an interactive video drama-based intervention in post-primary schools in Northern Ireland

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Background: Adolescent men have a vital yet neglected role in reducing unintended teenage pregnancy (UTP). There is a need for gender-sensitive educational interventions.

Objectives: To determine the value and feasibility of conducting an effectiveness trial of the *If I Were Jack* Relationship and Sexuality Education (RSE) intervention in a convenience quota sample of post-primary schools in Northern Ireland. Secondary objectives were to assess acceptability to schools, pupils (male/female, aged 14–15 years) and parents/guardians; to identify optimal delivery structures and systems; to establish participation rates and reach, including equality of engagement of different socioeconomic and religious types; to assess trial recruitment and retention rates; to assess variation in normal RSE practice; to refine survey instruments; to assess differences in outcomes for male and female pupils; to identify potential effect sizes that might be detected in an effectiveness trial and estimate appropriate sample size for that trial; and to identify costs of delivery and pilot methods for assessing cost-effectiveness.

Design: Cluster randomised Phase II feasibility trial with an embedded process and economic evaluation.

Intervention: A teacher-delivered classroom-based RSE resource – an interactive video drama (IVD) with classroom materials, teacher training and an information session for parents – to immerse young people in a hypothetical scenario of Jack, a teenager whose girlfriend is unintentionally pregnant. It addresses gender inequalities in RSE by focusing on young men and is designed to increase intentions to avoid UTP by encouraging young people to delay sexual intercourse and to use contraception consistently in sexual relationships.

Main outcome measures: Abstinence from sexual intercourse (delaying initiation of sex or returning to abstinence) or avoidance of unprotected sexual intercourse (consistent correct use of contraception). Secondary outcomes included Knowledge, Attitudes, Skills and Intentions.

Results: The intervention proved acceptable to schools, pupils and parents, as evidenced through positive process evaluation. One minor refinement to the parental component was required, namely the replacement of the teacher-led face-to-face information session for parents by online videos designed to deliver the intervention to parents/guardians into their home. School recruitment was successful (target 25%, achieved 38%). No school dropped out. Pupil retention was successful (target 85%, achieved 93%). The between-group difference in incidence of unprotected sex of 1.3% (95% confidence interval 0.55% to 2.2%) by 9 months demonstrated an effect size consistent with those reported to have had meaningful impact on UTP rates (resulting in an achievable sample size of 66 schools at Phase III). Survey instruments showed high acceptability and reliability of measures (Cronbach's alpha: 0.5–0.7). Economic evaluation at Phase III is feasible because it was possible to (1) identify costs of delivering *If I Were Jack* (mean cost per pupil, including training of teachers, was calculated as £13.66); and (2) develop a framework for assessing cost-effectiveness.

Conclusion: Trial methods were appropriate, and recruitment and retention of schools and pupils was satisfactory, successfully demonstrating all criteria for progression to a main trial. The perceived value of culture- and gender-sensitive public health interventions has been highlighted.

Future work: Progression to a Phase III effectiveness trial.

Trial registration: Current Controlled Trials ISRCTN99459996.

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List of abbreviations

A level	Advanced level	NISRA	Northern Ireland Statistics and Research Agency
ASSIST	A Stop Smoking In Schools Trial	PC	pastoral care
BHSCT	Belfast Health and Social Care Trust	PD	personal development
BT	British Telecom	PHA	Public Health Agency
CCEA	Council for the Curriculum, Examinations and Assessment	PI	principal investigator
CONSORT	Consolidated Standards of Reporting Trials	PPI	public and patient involvement
DHSSPS	Department of Health, Social Services and Public Safety	QUB	Queen's University Belfast
DVD	digital versatile disc	RC	Roman Catholic
FAST	First-aid Advice and Safety Training	RCT	randomised controlled trial
GCSE	General Certificate of Secondary Education	RE	Religious Education
HSC R&D	Health and Social Care Research and Development Office of Northern Ireland	RIPPLE	Randomized Intervention of Pupil-Led sex Education
ICC	intraclass correlation coefficient	RSE	Relationship and Sexuality Education
ID	identification number	SD	standard deviation
ISRCTN	International Standard Randomised Controlled Trial Number	SE	standard error
IT	Information Technology	SES	socioeconomic status
ITT	intention to treat	STAMPP	Steps Towards Alcohol Misuse Prevention Programme
IVD	interactive video drama	STI	sexually transmitted infection
LLW	Learning for Life and Work	TUPS	Intentions to Avoid Teenage Unintended Pregnancy scale
MRC	Medical Research Council	UPS2	upper pay scale
NI	Northern Ireland	UTP	unintended teenage pregnancy
NICTU	Northern Ireland Clinical Trials Unit	VP	vice principal
NIHR	National Institute for Health Research	WHO	World Health Organization

Plain English summary

Currently available educational approaches designed to lower unintended teenage pregnancy (UTP) focus primarily on girls.

This study aimed to trial a Relationship and Sexuality Education (RSE) teacher-delivered resource about young men and UTP called *If I Were Jack* in post-primary schools in Northern Ireland. The study assessed how acceptable and useful it was to teachers, pupils (male and female in mixed-sex classrooms) and parents in different types of schools and compared the findings obtained in four schools that used *If I Were Jack* with those in four schools that continued to use their usual approach to RSE. The study also aimed to pilot methods and to determine if it would be possible and worthwhile to conduct a large-scale UK-wide trial of the resource, which would determine if it might actually contribute to the reduction of teenage pregnancy rates.

If I Were Jack aims to help teenagers to imagine the situation of a teenage boy who has just discovered that his girlfriend has become unintentionally pregnant. It is designed to reduce UTP by encouraging teenagers to decrease sexual risk-taking behaviour that might result in unintended pregnancy either by delaying sexual intercourse or by consistently using contraception in sexual relationships.

If I Were Jack was acceptable to participating schools, pupils and parents and the study methods were suitable for collecting information from pupils. The findings also suggested that it would be possible to conduct a large-scale trial to examine the effectiveness of the resource in avoiding teenage pregnancy.

Scientific summary

Background

The *If I Were Jack* intervention aims to increase the intention of both boys and girls to avoid unintended teenage pregnancy (UTP) and addresses gender inequalities in Relationship and Sexuality Education (RSE) provision by explicitly focusing on young men and teenage pregnancy. The need for gender-sensitive interventions to address teenage pregnancy has been highlighted as a global health need by the World Health Organization and recommended in systematic reviews. The intervention has been designed specifically for use across the range of schools in Northern Ireland (NI), but it is based on international research regarding effective RSE interventions.

Teenage pregnancy remains a worldwide public health concern. The UK has the highest rate of adolescent pregnancy in Western Europe. Although rates of teenage pregnancy have been gradually falling across the UK since 2002, the birth rate for girls aged under 20 years in England and Wales remains high at 37.4 per 1000 in 2014. In real terms, just under 26,000 women under the age of 20 years became pregnant in England and Wales in 2014 and approximately half of these pregnancies ended in legal abortion, reflecting the potentially unintended or unwanted nature of these conceptions. The conception rate for Scotland was 37.7 per 1000 in 2013 (last available data). In NI, abortion is illegal and is considered lawful only in exceptional circumstances in which the life of the pregnant woman is at immediate risk or if there is a risk of serious injury to her physical or mental health. Reflecting this different legal framework, government targets around reducing teenage pregnancies in NI relate to births and not conceptions. In NI, the birth rate to teenage mothers per 1000 of the female population aged 13–19 years in 2014 was 10.3 per 1000 young women (a total of 839 births). The rate for young women in the most deprived areas was nearly 30 per 1000.

Although the life course for teenage parents is not universally negative, the social disadvantage and exclusion that are linked to teenage pregnancy are considered problematic. UTP can lead to considerable adverse health problems for teenagers and their infants, as well as generate enormous emotional, social and economic costs for adolescents, their families and society. Although UTP is a complex phenomenon that cannot be prevented through RSE alone, high-quality RSE is an essential component in the process of reducing unintended pregnancy rates, as well as being a vital aspect of improving holistic sexual health and well-being. Reflecting the importance of RSE, the governments of NI, England and Scotland all emphasise the policy importance of the reduction of teenage pregnancy rates via the implementation of RSE in schools as a key objective in current sexual health policies.

The UK government and the devolved parliaments and assemblies all emphasise the policy importance of decreasing conception rates in those aged under 18 years and increasing sexual health precaution behaviours in teenagers via the implementation of RSE in schools as a key objective in current sexual health policies. Drawing from robust representative epidemiological data of school-aged children across the UK [Inchley J, Currie D, Young T, Samdal O, Torsheim T, Augustson L, *et al.*, editors. *Growing Up Unequal: Gender And Socioeconomic Differences in Young People's heAlth and Well-Being. Health Behaviour in School-aged Children (HBSC) Study: International Report from the 2013/2014 Survey*. Copenhagen: World Health Organization; 2016, and Northern Ireland Statistics & Research Agency. *Young Persons' Behaviour & Attitudes Survey 2011*. Belfast: Northern Ireland Statistics & Research Agency; 2011], it is known that between 25% and 33% of 15-year-olds are having sex. Looking more closely in these surveys at the rates of unprotected sex for this age group, we can determine a rate of 2.8% reporting unprotected sex (overall in England, Wales, Scotland and NI) (sample $N = 7904$, and $n = 224$ reporting unprotected sex).

Objectives

The study aimed to determine the value and feasibility of conducting a Phase III effectiveness trial of the *If I Were Jack* RSE intervention in post-primary schools in NI. Secondary objectives of the study were to (1) assess the acceptability of the intervention to schools (principals and RSE teachers), male and female pupils (Year 11, aged 14–15 years) and parents; (2) identify optimal delivery structures and systems for the delivery of the resource in the classroom; (3) establish intervention participation rates and reach, including equality of engagement across schools of different socioeconomic and religious types; (4) assess trial recruitment and retention rates; (5) ascertain variation in normal RSE practice across the participating schools; (6) develop and refine survey instruments for use in a Phase III trial; (7) assess differences in outcomes for male and female pupils; (8) identify potential effect sizes that might be detected in an effectiveness trial and estimate appropriate sample size for that trial; and (9) identify the costs of delivering *If I Were Jack* and pilot the methods for economic analysis/cost-effectiveness in a Phase III trial.

Methods

The intervention

The *If I Were Jack* intervention is a classroom-based RSE resource intended for use by teenagers aged 14–15 years, based around a core component – a culturally sensitive interactive video drama (IVD) to immerse young people in a hypothetical scenario of a week in the life of Jack, a teenager who has just found out that his girlfriend is unintentionally pregnant. Additional components based around the IVD include classroom materials for teachers containing four detailed lesson plans with specific classroom-based and homework activities, which include group discussions, role-plays, worksheets and a parent–pupil exercise, a comprehensive training session for teachers/RSE facilitators, an information and discussion session for parents/guardians and detailed information brochures and factsheets about the intervention and UTP in general for schools, teachers, teacher trainers, young people and parents/guardians. The intervention is designed to be delivered by teachers over 4 weeks and aims to increase teenagers' intentions to avoid UTP by delaying sexual intercourse or consistently using contraception in sexual relationships and addresses gender inequalities in RSE by explicitly focusing on young men. To achieve this impact it uses an innovative combination of intervention components to (1) address identified deficits in existing RSE interventions; (2) develop a case scenario of an unintended pregnancy from a teenage male's point of view; (3) target a number of behavioural and sexual psychosocial variables that are key to decreasing sexual risk-taking behaviour (namely knowledge, attitudes, perceptions of risk, self-efficacy in communication, skills, beliefs about consequences, other sociocultural influences such as peer norms, gender norms and parental values and beliefs, beliefs about capabilities, and intention to avoid sexual risk-taking behaviour in order to help boys, as well as girls, build skills to avoid UTP); (4) provides comprehensive training and information about teenage pregnancy for teachers/RSE facilitators; and (5) incorporate communication about UTP within the classroom as well as with parents/guardians.

The development of the intervention was informed by baseline data on adolescent men's attitudes to UTP and the best available evidence regarding the components of effective RSE interventions. It was designed to fit with the RSE curriculum by a team of researchers working with experts from the Department of Health, Social Services and Public Safety, the Public Health Agency (PHA) of NI, and the Council for the Curriculum, Examinations and Assessment, as well as teacher trainers, teachers, parents and young people. Although produced in NI, the intervention would have strong cultural resonance for the UK as a whole. Further details on the *If I Were Jack* resource, including excerpts from the IVD and feedback from end users regarding the acceptability of the IVD, are available from: www.qub.ac.uk/IfIWereJack. Control schools will continue with their normal RSE practice.

Study design

A Phase II cluster randomised feasibility trial, with schools as the unit of randomisation, with embedded process and economic evaluations to determine recruitment, participation and retention rates; quality of

implementation; acceptability and feasibility of the intervention and trial procedures; and cost. The study also piloted the feasibility and acceptability of collecting demographic information and other sexual-psychosocial data (via a questionnaire) relating to measuring the proposed primary and secondary outcomes in a future larger Phase III trial. Each participating pupil was enrolled in the study for approximately 9 months and was asked to complete a questionnaire three times, at baseline and 5 and 9 months later. The process evaluation included semistructured interviews and focus group discussions with a sample of pupils, teachers, and parents/guardians regarding the acceptability and feasibility of the questionnaire, the intervention, and participation in the trial and also included observations of a sample of lessons and parent information sessions.

Study outcomes

Surrogate measures (alternatives to the use of UTP) used to create the composite primary outcome were abstinence from sexual intercourse (delay initiation of sex or return to abstinence) or avoidance of unprotected sexual intercourse (consistent correct use of contraception that does not include withdrawal or natural family planning). Secondary outcomes were drawn from the theoretical framework underpinning the intervention (theory of planned behaviour). The first of these was Knowledge to determine if pupils had increased knowledge about UTP. The second was Attitudes, in order to determine if pupils had increased awareness that men and women have roles and responsibilities in avoiding UTP, hold less stereotypical gender-related attitudes and have increased perception that most peers are not sexually active and use contraception when they are, and have increased perception that both parents (parent/child communication) and peers support abstinence and/or use of contraception. The third secondary outcome was Skills, in order to determine if pupils had increased self-efficacy to communicate about UTP and increased self-efficacy to avoid UTP. The final outcome was Intentions, in order to determine if pupils had higher anticipated regret about UTP and increased strengths of intention to avoid UTP.

Criteria for progression to main trial

The following issues were identified for consideration when using the results of the feasibility trial to decide whether or not to develop a protocol for a future Phase III effectiveness trial:

- The intervention is acceptable to schools (school principals and RSE teachers), pupils and parents/guardians; can be feasibly implemented by teachers in schools in NI; and any indications of necessary further development do not exceed the PHA's contribution of £20,000. If there is a consensus among school teachers that the *If I Were Jack* intervention would be of little value to other schools or if fundamental logistical problems in its delivery become evident and cannot be rectified, we would not proceed to trial.
- Recruitment, participation and retention rates are likely to be adequate for a main trial. We would expect high rates of recruitment, participation and retention. However, if we do not recruit at least 25% of schools approached we shall not proceed to trial. In addition, if we experience > 25% of parents withdrawing their children from the study or > 25% of pupils refusing to participate we shall not proceed to trial. Finally, in relation to retention, if < 85% of pupils complete the primary outcome measure at follow-up, we would not proceed to trial.
- Potential effect sizes indicate an achievable sample size.
- The survey instruments can be feasibly delivered and show acceptable reliability and validity.
- An economic evaluation can be feasibly conducted as part of the main trial.

Results

The intervention proved acceptable to schools, pupils and parents/guardians, as evidenced through positive process evaluation. One minor refinement in relation to the parental component was required, namely the replacement of the teacher led face-to-face information session for parents/guardians by online videos designed to deliver the information to parents/guardians into their home. Recruitment of schools was successful (target 25%, achieved 38%). Withdrawal from the study was also low (10%); no schools

withdrew, parental withdrawal of consent accounted for 6.8% of loss ($n = 70$) and pupil opt-out for 3.2% ($n = 32$). Pupil retention was successful (target 85%, achieved 93%).

The between-group difference in incidence of unprotected sex of 1.3% (95% confidence interval 0.5% to 2.2%) and intraclass correlation coefficient of 0.01, by 9 months' follow-up in the feasibility trial, demonstrated an effect size consistent with those reported to have had a meaningful impact on UTP rates (resulting in an achievable sample size estimate of 66 schools for a future Phase III effectiveness trial).

Survey instruments showed high acceptability and reliability of measures. The Male Role Attitudes scale, Sexual Socialisation Peer scale, Sexual Self-Efficacy scale and Intentions to Avoid an UTP scale all had high internal consistency (Cronbach's alpha in excess of 0.7), and Family Connectedness, Comfort Communicating about Pregnancy, Comfort Communicating about Contraception, Sexual Socialisation Total and the Sexual Socialisation Parent scales had satisfactory internal consistency (Cronbach's alpha: 0.5–0.7). The knowledge questions also worked well, showing good variability, except for one item, which will be deleted for a future Phase III effectiveness trial. The feasibility study also demonstrated that the survey instruments can be delivered to time in the recruited schools and that matching questionnaires across the data points was unproblematic using barcodes on questionnaires and envelopes. The instruments showed high acceptability, with the majority of participants stating that they felt comfortable in answering most of the questions in this questionnaire (80%, $n = 608$). Ninety-three (93%) of the pupils completed primary outcome at follow-up 2. Minor necessary changes to the questionnaire and classroom materials that became evident through process evaluation will also be addressed.

An economic evaluation at Phase III is feasible because during the feasibility study it was possible to (1) identify costs of delivering *If I Were Jack* (mean cost per pupil, including training of teachers, was calculated as £13.66); and (2) develop a framework for assessing cost-effectiveness. Additional secondary outcome measures including frequency of sexual intercourse, contraception use and diagnosis of sexually transmitted infections that will assist with economic evaluation at Phase III were shown to be feasible to collect during this Phase II feasibility study.

Conclusions

Trial methods were appropriate, and recruitment and retention of schools and pupils was satisfactory, successfully demonstrating all criteria for progression to a future Phase III effectiveness trial.

Trial registration

This trial is registered as ISRCTN99459996.

Funding

Funding for this study was provided by the Public Health Research programme of the National Institute for Health Research.

Chapter 1 Research aims and objectives

Introduction

This chapter details the aims and objectives of the research study, ethics approval, study relevant documents, Steering Group arrangements, stakeholder representation and public and patient involvement (PPI) in the research.

Aims and objectives

Primary aim

The aim of the study was to determine the value and feasibility of conducting an effectiveness trial of the *If I Were Jack* Relationship and Sexuality Education (RSE) intervention in post-primary schools.

Secondary objectives

The research aimed to achieve the following secondary objectives:

- assess the acceptability of the intervention to schools (school principals and RSE teachers), male and female pupils and parents
- identify optimal delivery structures and systems for the delivery of the resource in the classroom
- establish participation rates and reach including equality of engagement across schools of different socioeconomic and religious types
- assess trial recruitment and retention rates
- assess variation in normal RSE practice across the participating schools
- refine survey instruments as a result of cognitive interviews with male and female pupils
- assess differences in outcomes for male and female pupils
- identify potential effect sizes that might be detected in an effectiveness trial and estimate appropriate sample size for that trial
- identify the costs of delivering *If I Were Jack* and pilot methods for assessing cost-effectiveness in a future trial.

Ethics approval

Ethics approval for the study was granted by the Research Ethics Committee of the School of Nursing and Midwifery, Queen's University Belfast (QUB) (reference 04.02.02.V2).

Study protocol, participant letters of invitation, information leaflets, consent forms and data collection instruments

For the protocol (version 2), see or <http://dx.doi.org/10.1016/j.ijer.2014.08.003>.

For participant letters of invitation, information leaflets and consent forms, see *Appendix 1*.

For data collection instruments, see *Appendix 2*.

Protocol amendments

National Institute for Health Research (NIHR) Protocol version two changes (20 April 2015) included the following:

1. Updated version number.
2. Updated date of version.
3. Changed Clinicaltrials.gov registration number (NCT02092480) to an International Standard Randomised Controlled Trial Number (ISRCTN99459996).
4. Changed all references to seven schools to eight schools in the text and the flow chart.
5. Changed all references to three control schools to four control schools in the text and the flow chart.
6. Adjusted the sample size calculation from 630 to 720 to reflect the increased number of schools.
7. Added in a stratification subsection in section 5.b.
8. Added in a randomisation subsection in section 5.b.
9. Updated *Appendix 3* (outcome measures) by removing the 'Beliefs about Consequences' outcome and the 'London measure of unplanned pregnancy' which occurred post pilot. These changes were due to low variability in responses and the low numbers of pregnancy, respectively. The newly developed Intention to Avoid Unintended Teenage Pregnancy (UTP) scale was added.
10. In this section *Process evaluation*, the following line was removed: 'Inquire into teacher trainer's views on the training materials for teachers'. This is because the researcher is delivering the teacher training.
11. Added the information video on YouTube (YouTube, LLC, San Bruno, CA, USA) to the Parents Information Evening section.
12. Changed the sample size estimate for parent focus groups from 25–95 to eight-20.

Stakeholder representatives, international advisory group, trial steering group and details of meetings

Stakeholder group

Ms Joanna Brown, RSE and Local Area Coordinator, Sexual Health Training Team, Belfast Health and Social Care Trust (BHSCT), Northern Ireland (NI), UK.

Dr Bernadette Cullen, Consultant in Public Health, Public Health Agency (PHA) of NI.

Ms Kathryn Gilbert, Curriculum and Assessment Programme Manager, Council for the Curriculum, Examinations and Assessment (CCEA), NI.

Dr Naresh Chada, Senior Medical Officer, Department of Health, Social Services and Public Safety (DHSSPS), NI.

Ms Janet Moore, DHSSPS.

International Advisory Group

Trial Steering Group

Professor Vivien Coates (Independent Member and Chairperson), Institute of Nursing and Health Research, School of Nursing, University of Ulster, NI.

Dr Suzanne Guerin (Independent Member), School of Psychology, University College Dublin, Ireland.

Dr Liam O'Hare (Member), Centre for Effective Education, School of Education, QUB.

Master Patrick Lynn (Independent Public Member/School Pupil).

Miss Chloe Templeton (Independent Public Member/School Pupil).

Dr Darrin Barr (Independent Public Member/School Principal).

Ms Grace McCarthy (Independent Public Member/School Teacher).

Ms Lisa Barr (Independent Public Member, Parent).

Dr Maria Lohan (Member and Chief Investigator), School of Nursing and Midwifery, QUB.

Dr Áine Aventin (Member), School of Nursing and Midwifery, QUB.

Dr Hannah-Rose Douglas (Independent Member), National Collaborating Centre for Women's and Children's Health, NI.

Trial Steering Group meetings

The Trial Steering Group met three times, on 9 October 2014, 11 May 2015 and 24 November 2015. For Trial Steering Group minutes see *Appendix 4*.

Public and patient involvement

The study was informed by several stakeholders:

1. Survey research with adolescents evaluating the *If I Were Jack* interactive film and a qualitative study with teachers.¹
2. In the intervention development phase (see *Chapter 3*), we convened a professional stakeholders' group (see above) of senior representatives from key government departments [Health and Safety Executive, PHA, DHSSPS, CCEA (Belfast, UK), and Department of Education Ireland] who, alongside teachers and pupils, were involved in designing the intervention.²
3. Prior to the pilot study for questionnaire development, we liaised with a young people's research group. This was an ad hoc group comprising the young people from the Trial Steering Group and additional members of a Young People's Advisory Group working on a similar study at QUB, in which Dr Lohan (Chief Investigator) was involved.
4. During the pilot study for questionnaire development (see *Chapter 4*).
5. During the feasibility trial through consultation with the Trial Steering Group, which included relevant independent and public lay membership (see above).
6. During the feasibility trial through process evaluation whereby we sought the views of teachers, pupils and parents regarding potential refinements to the intervention (see *Chapter 7*).

Chapter 2 Background and rationale for the study

Existing research: understanding unintended teenage pregnancy

Teenage pregnancy remains a worldwide public health concern.^{3,4} The UK has the highest rate of adolescent pregnancy in Western Europe.⁴ Although rates of teenage pregnancy have been gradually falling across the UK since 2002, the birth rate for girls aged under 20 years in England and Wales remains high, at 37.4 per 1000 in 2014.⁵ In real terms, just under 26,000 women under the age of 20 years became pregnant in England and Wales in 2014 and approximately half of these pregnancies ended in legal abortion, reflecting the potentially unintended or unwanted nature of these conceptions.⁶ The conception rate for Scotland was 37.7 per 1000 in 2013.⁷ In NI, abortion is illegal and is considered lawful only in exceptional circumstances in which the life of the pregnant woman is at immediate risk or if there is a risk of serious injury to her physical or mental health. Reflecting this different legal framework, government targets around reducing teenage pregnancies in NI relate to births and not conceptions. In NI, the birth rate to teenage mothers per 1000 of the female population aged 13–19 years in 2014 was 10.3 per 1000 young women (a total of 839 births).⁸ The rate for young women in the most deprived areas was nearly 30 per 1000.⁹

Although the life course for teenage parents is not universally negative,^{10,11} the social disadvantage and exclusion that are linked to teenage pregnancy are considered problematic.¹² UTP can lead to considerable adverse health problems for teenagers and their infants, as well as generate enormous emotional, social and economic costs for adolescents, their families and society.¹³ Although UTP is a complex phenomenon that cannot be prevented through RSE alone,^{14–20} high-quality RSE is an essential component in the process of reducing unintended pregnancy rates, as well as being a vital aspect of improving holistic sexual health and well-being.^{21–27} Reflecting the importance of RSE, the governments of NI, England and Scotland all emphasise the policy importance of the reduction of teenage pregnancy rates via the implementation of RSE in schools as a key objective in current sexual health policies.^{26–28}

Unprotected sex during teenage years is well established as the main proximate behavioural determinant of teenage pregnancy and is a commonly measured behavioural outcome in studies examining the impact of RSE interventions on teenage pregnancy.^{17,27,29} Research indicates that, although other behavioural determinants (such as frequency of sexual intercourse and number of sexual partners) are important, avoidance of unprotected sex via consistent use of contraception is central in explaining variation in levels of adolescent pregnancy.²²

A number of systematic reviews have identified the characteristics of effective RSE programmes that may have an impact on sexual risk-taking behaviours.^{19,30–36} These include the use of theoretically based interventions targeting sexual and psychosocial mediating variables such as knowledge, attitudes, self-efficacy, intentions, perceptions of risk, and perceptions of peer norms which are linked to sexual behaviour change; the use of culturally-sensitive and gender-specific interventions; the use of interactive modalities that promote personal identification with the educational issues and engagement of young people; the use of skills-building components; the involvement of parents in the RSE process; and facilitating linkages with support services.

Evidence supporting a theory-based approach

Providing a theoretically informed foundation for sexual health education programmes is considered key to effectiveness because it ensures that the most important determinants of young people's sexual behaviour are targeted.^{22,32,34,37–39} The underpinning theoretical framework for the intervention used in this study combines the well-established theory of planned behaviour^{40,41} and recent updates to this theory,^{42,43} which focus on the individual behavioural antecedents of an unplanned pregnancy along with an understanding of the broader socioenvironmental factors (such as social class) and underlying values (such as religiosity and gender ideologies) associated with the occurrence of teenage pregnancy.¹⁸ Interventions should target six

psychosocial mechanisms that research indicates are related to a reduction in risk-taking behaviour: knowledge, skills, beliefs about consequences, social influences, beliefs about capabilities and intentions.^{19,44,45}

Evidence supporting the use of culturally relevant and gender-specific interventions

The World Health Organization (WHO),^{46,47} recent systematic reviews commissioned by the US-based National Campaign to Prevent Teen Pregnancy,^{48,49} and the NIHR,⁵⁰ among others,^{1,22,51–54} recognise that adolescent men have a vital yet neglected role in reducing teenage pregnancies, and that there is a pressing need for RSE interventions designed especially for them.

In relation to cultural relevance, research suggests the need to engage with young people both empathetically and cognitively in order to increase the relevance of the issues being raised.^{14,23,30,31,55} As Ingham and Hirst²⁴ have noted, it is important to harness the potential for sex education to be keenly anticipated, especially by those who are less engaged in the wider school curriculum, a factor that was identified as a possible barrier to impact.⁵⁰

Evidence relating to socioeconomic position and inequalities

Research suggests that interventions targeting only schools in disadvantaged areas are insufficient for achieving population-level reductions in teenage pregnancy.^{56,57}

Evidence supporting the use of interactive computer-based interventions

Recent systematic reviews have shown the value of interactive-computer-based interventions,^{34,35,55} and a meta-analysis examining these reviews in relation to the theoretical mediators of safer sex³⁶ concluded that they were successful in impacting knowledge, attitudes and self-efficacy relating to sexual health.

Evidence supporting the use of skills-building components

Reviews and trials of health promotion and educational interventions show that simply providing information does not lead to behaviour change and that instead it is necessary to support young people to develop their own communication skills in relation to preventing risky sexual behaviours.^{14,17,19,21–23,30,34,47,58} A recent NIHR Health Technology Assessment systematic review¹⁹ of the effect of interventions aiming to encourage young people to adopt safer sexual behaviour found that school-based interventions that provide information and teach young people sexual health negotiation skills can bring about improvements in behaviour-mediating outcomes such as knowledge, attitudes and self-efficacy. The authors noted that these variables are no less valuable than behavioural variables because they provide young people with a solid foundation on which to make sexual decisions.

Evidence supporting the involvement of parents in Relationship and Sexuality Education

Although evidence suggests that schools are an important context for sex education,^{14,48,59} recent systematic reviews have also shown that programmes that reach beyond the classroom (including multifaceted approaches with a parental or community component) are more effective,^{19,25,60} particularly with adolescent men.⁴⁸ In particular, factors such as parental monitoring and supervision and familial communication have been associated with adolescent sexual behaviours.^{61,62} Teenagers who can recall a parent communicating with them about sex are more likely to report delaying sexual debut and increased condom and contraceptive use.^{63–65}

Most parents do, however, recognise the importance of speaking to their children about sex and most would like more resources to help them in this regard.⁶⁶ Furthermore, many teenagers report parents as a primary source of information on sexual health matters.⁶⁷ The unprecedented growth in the use of online and mobile technology over the past few decades by people of all ages presents opportunities for increasing the reach (and decreasing the perceived embarrassment) of parental involvement in sex education.⁶⁸ More than 20 years ago, Miller *et al.*⁶⁶ found that a home-based video sex education intervention designed to make it easier for parents to talk to their teens about sex was effective in increasing the frequency of parent–teen communication regarding sexual topics. The use of ‘education entertainment’ for addressing health issues

has become increasingly common since then⁶⁹ and, in recent times, studies^{61,68,70} have demonstrated the importance of embracing such modalities as engaging adjuncts to school-based education.

Rationale for the feasibility trial

The study is justified on the following grounds.

Previous research by members of the study team

When we used an earlier version of this interactive video drama (IVD), a component of the intervention in this study (see *Chapter 3*) as part of a research project on teenage males and unintended pregnancy, 85% of a sample of male pupils in Ireland ($n = 360$) and 72% in Australia ($n = 386$) agreed or strongly agreed with the statement that it 'helped me understand the effect an unplanned pregnancy would have on a guy like me'. In Ireland and Australia, 79% and 69%, respectively, agreed or strongly agreed that the IVD 'made me realise that I should never get myself in that situation'.⁷¹

The public health concern of teenage pregnancy and the potential reach of targeted school-based interventions to provide young people with a solid foundation on which to make sexual decisions

The core aim of the *If I Were Jack* intervention is to use an evidence-based process to allow schools to provide pupils with opportunities for exploring the issues surrounding teenage pregnancy and parenthood with reference to the individual, family, community and society. If it is acceptable and effective, it has the potential to be rolled out to large numbers of boys and girls attending schools across the UK and to be of benefit to several groups of people. In 2011/12 there were 24,251 pupils in Year 11 in the 216 mainstream post-primary schools in NI⁷² and 551,800 pupils in the 3268 state-funded secondary schools in England.⁵⁷ Pupils will benefit from an engaging educational resource. Parents will benefit from a process designed to involve and support them in communicating with their child. RSE teachers will benefit because the resource will provide them with a stimulus for engaging pupils in an immersive decision-making experience from the point of view of a teenage male, followed by guided classroom-based activities.

Teenage pregnancy is both an outcome of, and a contributor to, inequalities in health.¹² The aggregate projected spend for 2013–20 for treating both unintended pregnancy and sexually transmitted infections (STIs) (for all ages) across the UK is estimated to be between £84.4B and £127B. This is based on a projected spend of £11.4B of NHS costs as a result of unintended pregnancy and STI costs, and between £73B and £115.3B of wider public sector costs.⁷³ The NI government estimates the cost to the Exchequer of teenage pregnancies at £20,000 per teenage mother on the basis that a teenage pregnancy effectively withdraws the mother from the labour market (not in education, employment or training) for at least 18 months and accounting for unemployment benefits and administration, plus tax revenue forgone.²⁶ Our population-based approach is consistent with the evidence that universal interventions are necessary to achieve population-level reductions in teenage pregnancies.^{56,74–76}

This study will begin a process of robust evaluation that may also lead to the roll-out across the UK and international applications of the intervention

Internationally, policy-makers and researchers have called for scientifically evaluated school-based RSE interventions.^{16,21–25,77,78} A successful feasibility would underpin the development of a UK-wide Phase III trial. The intervention has been designed specifically for use in NI, but it is based on international research regarding effective RSE interventions. Although the video drama features NI actors, there is no specific reference to NI in the video and we believe that it would have strong cultural resonance in the rest of the UK. Furthermore, although the accompanying materials make specific reference to the NI curriculum and legislation in NI governing termination of pregnancy, the costs of making changes to these references so that the materials could be used in contexts across the UK would be negligible.

The need to develop and evaluate age- and gender-specific Relationship and Sexuality Education resources

The need for gender-sensitive interventions to address teenage pregnancy has been highlighted as a global health need by the WHO^{46,47} and has been recommended in systematic reviews.^{19,48,49} Addressing teenage males' RSE is an important mechanism for promoting positive development and improving the lives of all young adults, especially those suffering the effects of various types of disadvantage.^{48,51–53,79}

A recent inspection by the Education and Training Inspectorate of RSE implementation in post-primary schools in NI identified the need for RSE resources for older adolescents, especially at Key Stage 4 (age 14+ years).⁸⁰ The absence of such resources is thought to be a demotivating factor, making RSE more difficult for some schools to implement. Internationally, there has also been demand for age-appropriate school-based RSE interventions.^{16,21–25,77,78}

We aim to initiate a process of robust scientific evaluation, which will ultimately produce generalisable findings especially relating to gender-specific interventions. The intervention we propose is gender-inclusive in terms of intent and impact and it can be used in mixed-sex classrooms, but is gender-specific in that it specifically targets the inclusion of adolescent men by developing an interactive film from a man's point of view.

The strengths of the If I Were Jack intervention

The *If I Were Jack* intervention is grounded in empirical research on adolescent men's attitudes to UTP; was developed in consultation with key health and education experts, pupils, teachers and parents; and is informed by the best available evidence regarding the development of classroom-based RSE interventions. It is predicted to impact on a number of behavioural and psychosocial mediating variables, which research suggests decrease sexual risk-taking behaviour. It uses an innovative combination of intervention components which address deficits in existing RSE interventions and aim to maximise potential impact.

The right place for this study

This research is necessary to address the deficit of research on high-quality RSE interventions in NI. Although RSE is mandatory in NI, its provision in schools is known to be underdeveloped and highly variable.^{9,80–83} In addition, given that RSE in NI is underdeveloped, we are more likely to be able to test the efficacy of the intervention in NI as a prelude to a Phase III trial to test its effectiveness. In our preliminary research and in working through a partnership model to develop this study, we believe that we are in a strong position to overcome the problems in implementing RSE in NI and have already found the resource to be culturally sensitive and acceptable to statutory stakeholders and schools.

The educational and policy demands for such an intervention

The letters of support from across the health and educational sector of the UK (including, in NI, the Chief Medical Officer, PHA NI, DHSSPS and CCEA) identify the need for and support this study. Several stakeholder organisations are also offering in-kind contributions in terms of membership of a study stakeholder's group along with a contribution of £20,000 co-funding from PHA. This stakeholder investment in this project attests to the widely held need to evaluate evidence-based, theory-informed RSE resources that clearly target boys as well as girls in relation to unintended pregnancy and improving sexual health and well-being.

Chapter 3 The intervention

Overview of the intervention

The *If I Were Jack* intervention² is a classroom-based RSE resource intended for use by teenagers aged 14–15 years, based around a core component – a culturally sensitive interactive IVD to immerse young people in a hypothetical scenario of a week in the life of Jack, a teenager who has just found out that his girlfriend is pregnant. It is designed to be delivered by teachers over 4 weeks, and also incorporates communication with parents/guardians within the RSE process.

It is composed of a number of components:

- the *If I Were Jack* IVD, which asks pupils to put themselves in Jack's shoes and consider how they would feel and what they would do if they were Jack
- classroom materials for teachers containing four detailed lesson plans with specific classroom-based and homework activities including group discussions, role-plays, worksheets and a parent–pupil exercise
- a 60-minute face-to-face training session for teachers wishing to implement the intervention
- a 60-minute information and discussion session for parents/guardians delivered by RSE teachers (also presented as a brief 6-minute YouTube video delivered by the principal investigator (PI) containing an overview of the key points, for those who were unable to attend)
- detailed information brochures and factsheets about the intervention and UTP in general for schools, teachers, teacher trainers, young people and parents.

The IVD is interactive in that the film pauses throughout with questions that invite users to imagine being Jack. On individual computers, they watch Jack as he thinks about what his friends and parents might say, chats to his girlfriend and attends a pregnancy counselling session. The user answers questions about how they would think, feel and react in these situations and ultimately decide upon a pregnancy resolution option. Although targeted specifically at young men, through the presentation of the case scenario of an UTP from a teenage male's point of view, it can also be used by young women and in mixed-sex classrooms. By asking both girls and boys to empathise with Jack and ask themselves how they would think and feel if they were in his situation, it is designed to make explicit the gender assumptions around roles and responsibilities for teenage pregnancy while opening them up for reflection and negotiation.

The face-to-face teacher training session lasted for 60 minutes and was mandatory for those delivering the intervention. It included an overview of the *If I Were Jack* feasibility trial and the components of the intervention, its underlying theory and key messages. Teachers were given a full demonstration of the IVD and detailed information on the accompanying activities and how they should be implemented. They were advised that they should stick as closely as possible to the implementation guidelines detailed in the 'information for teachers' booklet. However, as implementation processes were being piloted as part of the study, they were informed that they could vary implementation if necessary and were asked to record any variation in implementation in the implementation log booklets.

The development of the intervention was informed by empirical research on adolescent men's attitudes to UTP and the best available evidence regarding the components of effective RSE interventions. It was designed to fit with the RSE curriculum by a team of researchers working with experts from the DHSSPS, PHA, and CCEA, as well as teacher trainers, teachers, parents and adolescents.

The intervention includes an innovative combination of different components, content and educational objectives which provide pupils with educational information and opportunities for communication with peers and parents, skills practice, reflection and anticipatory thinking (see *Appendix 5*). The design and

development of the *If I Were Jack* intervention is detailed in full in Aventin *et al.*² and addresses identified deficits in existing RSE interventions. Additional intervention components, which are based around the IVD, include classroom materials, a comprehensive training session for teachers/RSE facilitators and an information and discussion session for parents. For the feasibility trial this information was also presented as a brief 6-minute YouTube video delivered by the PI containing an overview of the key points, for those who were unable to attend. Further information about the intervention, including excerpts from the film and feedback from end users regarding the acceptability of the IVD, is also available from the project website (see www.qub.ac.uk/IfIWereJack).⁸⁴

The intervention is designed to increase adolescents' intentions to avoid an UTP by delaying sexual intercourse or consistently using contraception in sexual relationships. To achieve this impact, it targets six psychosocial mechanisms (see *Appendix 5*), which theory and research suggest are key to decreasing sexual risk-taking behaviour: (1) knowledge; (2) skills; (3) beliefs about consequences; (4) other sociocultural influences such as peer norms, gender norms and parental values and beliefs; (5) beliefs about capabilities; and (6) intentions.^{40,85–87} The *If I Were Jack* theory of change model is detailed in *Figure 1*. The intervention aims to maximise potential impact by incorporating components, which some studies have indicated are key elements of effective RSE interventions (e.g. interactive media,^{34,35} peer discussion^{25,37} and parental involvement).⁸⁸ In brief, we hypothesise that by encouraging personal identification with the UTP scenario in the IVD, we engage pupils in an exercise of the imagination whereby they stop and think about the consequences that an UTP might have on their current life and future goals. This identification and reflection process is reinforced by providing knowledge about the risks and consequences of UTP and ways to avoid it and offering opportunities to practice communicating about UTP with peers and parents/guardians (activities that also increase awareness of peer norms and personal and familial values and beliefs about sexual behaviour and unintended pregnancy). We hypothesise that by targeting these psychosocial factors, we impact on teenagers' sexual behaviour via pathways through their intention to avoid UTP.

Methods

Development of the intervention was a two-stage process (*Figure 2*) informed by the Medical Research Council (MRC) Framework.⁸⁹ The process began with a systematic review of the literature on adolescent men and UTP.⁹⁰ Following this, a version of the IVD was developed as a data collection tool and used to develop the empirical evidence base on adolescent men's attitudes and decision-making in relation to an UTP (see *Chapter 2, Previous research by members of the study team*).¹ Feedback from pupils, teachers and educational specialists indicated that this version of the IVD had potential to be redeveloped as part of an intervention. This resulted in stage 2 of the process, in which a further systematic review of the literature on the characteristics of effective RSE was conducted. The IVD was redeveloped, which involved the filming of a new Northern Irish version (for the purposes of cultural relevancy) and the development of additional intervention materials informed by the theory of change model depicted in *Figure 1* and by consultation with stakeholders.

Results

Stage 1: preliminary research and development of the interactive video drama

Systematic review

A systematic review of the literature on young men's attitudes towards UTP and parenthood indicated a number of potential psychosocial influences on young men's attitudes towards UTP and pregnancy outcome decisions.⁹⁰ These included social class, religiosity, gender identity, masculinity, the idealisation of pregnancy and parenthood, and attitudes and subjective norms regarding how significant others (such as parents, friends and partners) would expect them to behave in such a situation. The *If I Were Jack* intervention targets these psychosocial influences as key mechanisms.

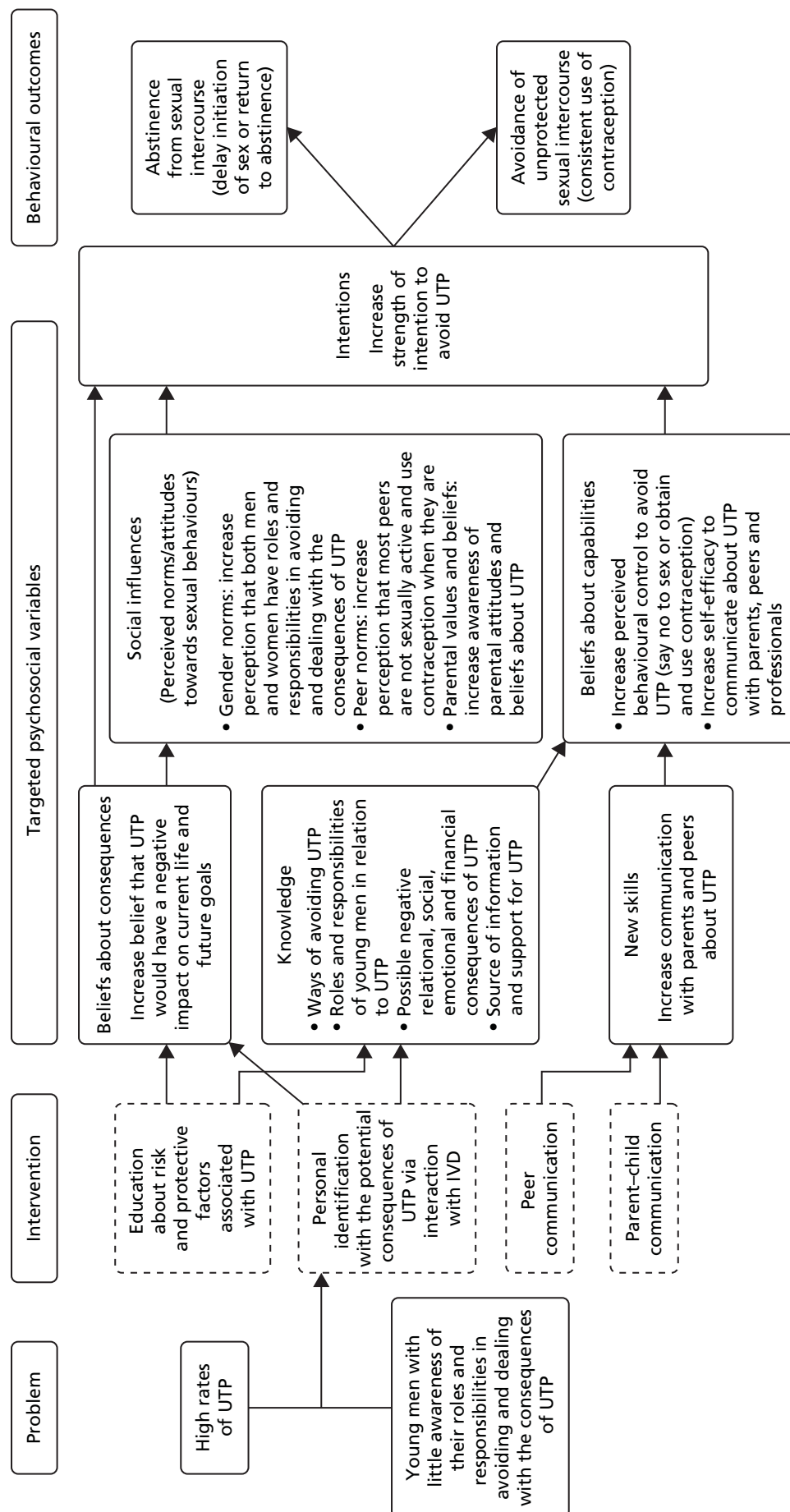


FIGURE 1 If I Were Jack theory of change model.

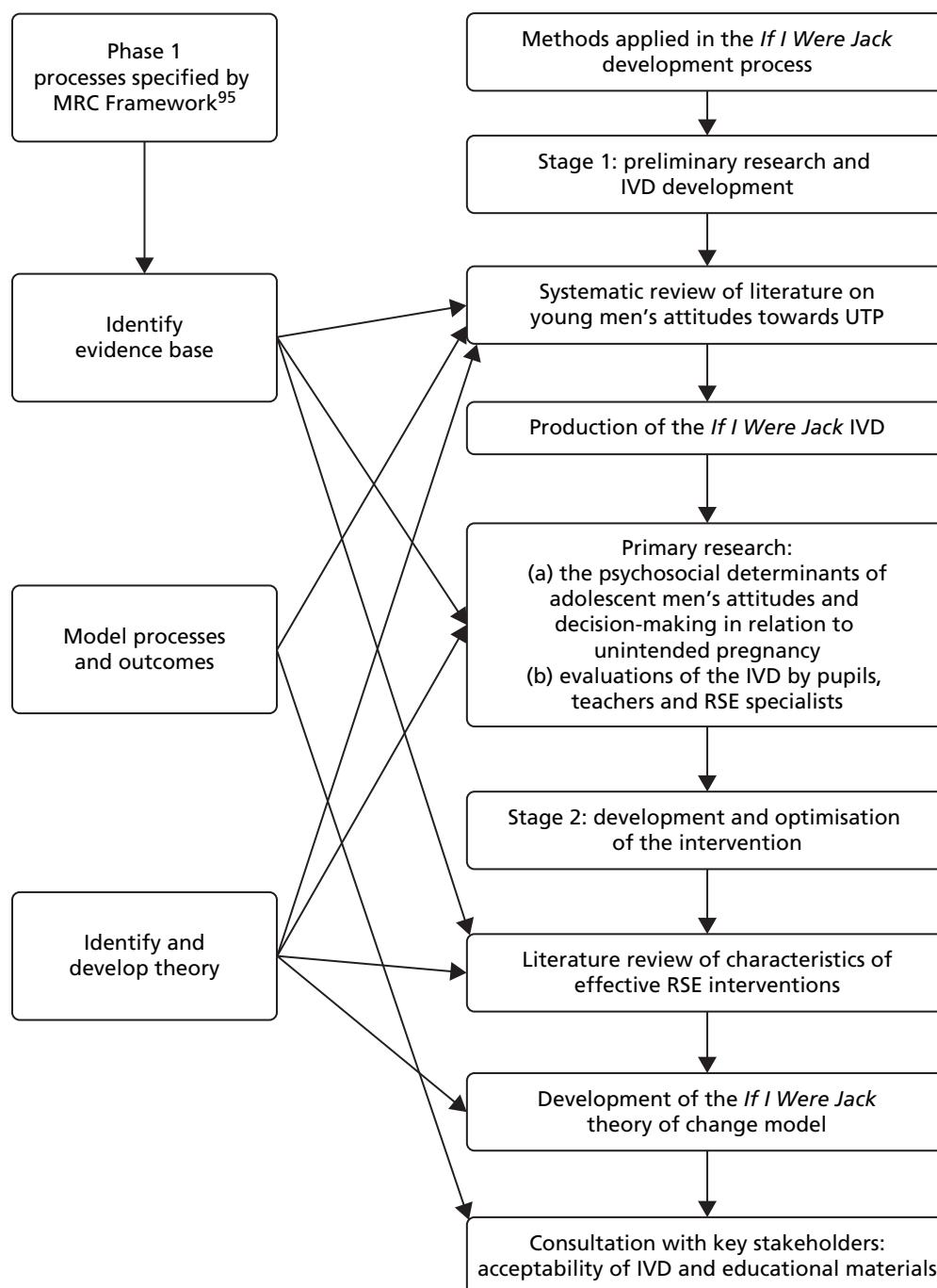


FIGURE 2 The *If I Were Jack* development process.

The *If I Were Jack* IVD was inspired and modified (with permission) from a version used in an Australian study of adolescent men and pregnancy.⁹¹ Irish and Northern Irish versions were filmed (to be more culturally and contextually relevant), informed by previous Irish research⁹² and in consultation with an expert advisory group and youth drama groups, first for use as a data collection tool in a study examining influences on young Irish men's attitudes and decision-making in relation to a hypothetical UTP.¹ A significant change included the addition of a third pregnancy outcome choice, namely 'adoption', in addition to 'keeping the baby' and 'abortion'. Evaluation supported the notion of developing it as an educational resource and offered suggestions for how it might be optimised for use in the classroom.⁷¹ There was agreement among participants that it was authentic in its representation of a believable UTP scenario; engaging to users because of its interactive modality; unique in its representation of the male role in UTP and use of high-quality drama; easy to use; and held potential for inclusion within broader RSE curriculum.⁷¹ Formative evaluation of the original Australian

version indicated that the IVD had potential for achieving key educational and health promotion outcomes in relation to raising awareness around UTP in young men's lives.⁹³ Further development and evaluation of the existing Northern Irish IVD into an educational intervention ensued in stage 2 of the production process.

Stage 2: development and optimisation of the intervention

Stage 2 focused on developing the intervention. This involved redevelopment of the IVD and design of accompanying classroom materials based on evidence regarding the characteristics of effective RSE interventions and theoretical understanding of the determinants of behavioural change. Also central to stage 2 was consultation in relation to the content (see *Chapter 1, Public and patient involvement*).

Identifying the evidence and modelling theory

A number of systematic reviews have identified the characteristics of RSE interventions that have been effective in changing sexual risk-taking behaviours.^{19,30,33–35} The *If I Were Jack* intervention represents an innovative combination of these different elements. Providing a theoretically informed foundation for sexual health education programmes is considered key to effectiveness because it ensures that the most important determinants of young people's sexual behaviour are targeted.^{21,34,37} The *If I Were Jack* intervention is broadly based around the theory of planned behaviour⁴⁰ but also draws on other psychosocial theories which emerged as important during the systematic review stage described above. The *If I Were Jack* theory of change model is depicted in *Figure 1*, the development of which (informed by Kirby *et al.*⁹⁴) included four steps:

1. identification and selection of the health goal (reduction of UTP rates)
2. identification and selection of important related behaviours (abstinence from sexual intercourse and avoidance of unprotected sexual intercourse)
3. identification and selection of important risk and protective factors (targeted psychosocial variables as indicated by theory and research)
4. identification and selection of intervention components (see below).

Developing the content and components

Educational outcomes were defined for each of the user groups (pupils, teachers, teacher trainers and parents) based on the targeted psychosocial variables detailed in the theory of change model (see *Figure 1*) and then considering possible activities that might help young people to achieve this outcome. An overview is provided in *Appendix 5*.

Refining the content in consultation

The draft IVD and educational materials were reviewed by a steering group and amended following feedback. Further consultation with relevant stakeholders – teachers, pupils and parents – regarding their acceptability was also undertaken. This is described in full in Aventin *et al.*² Notable refinements made as a result included the following.

Addressing the issue of abortion

Although the intervention is non-directive in terms of pregnancy outcome options, stakeholders were concerned that the mention of 'abortion' might negatively impact on uptake, in particular in schools that have an anti-abortion ethos. This issue was addressed by changing the order in which the pregnancy outcome options were displayed in the IVD; including information about the legal status of abortion (locally); and changing wording that might be interpreted as pro-abortion. In addition, teachers were reminded repeatedly during the teacher training session and in the classroom materials that they have the opportunity to state the school ethos and RSE policy and that the intervention allows for this flexibility.

Making it gender sensitive

Although the intervention was developed specifically for teenage males, preliminary research suggested that it would also be suitable for use by teenage women. The learning objective was to introduce the topic of UTP through the male perspective, arguably a fresh perspective, but to use this as a starting point to

discuss both male and female perspectives and to explore similarities as well as differences. Thus, girls are also asked through this intervention to imagine 'If I Were Jack'. Following consultation, additional amendments made to address this issue involved the addition of three questions to the IVD which referred to how the female character may be feeling (i.e. 'If I were Jack, how do I think Emma would be feeling now?'). Such questions allowed for further exploration of the female partner's perspective while retaining the focus of the exercise on the perspective of the male character.

Increasing credibility

Increasing the credibility of the intervention to gatekeepers (schools, teachers and parents) was achieved by developing a dedicated website for the intervention. The website includes, among other features, expert stakeholders' and teachers' audio- and video-recorded testimonies.

Increasing accessibility

The IVD was developed for the internet, adapting the previous version, which was delivered to the end user on digital versatile disc (DVD), and transforming it into the online environment.

Discussion

Effective RSE interventions require rigorous development processes and transparent reporting to ensure both substantive and process-related knowledge transfer. The design and development of the *If I Were Jack* intervention benefited from the guidance provided by the MRC framework for the development and evaluation of complex interventions⁸⁷ and followed the recommended process of identifying the evidence base, identifying theory relating to the phenomenon of young men and UTP and modelling the processes and outcomes of implementing the intervention through preliminary research and consultation with key stakeholders. In applying the framework in the real world we learned lessons, which both complement and extend beyond the guidance that accompanies it, and gained practical insight into a development process that might be useful for others. Three key lessons are detailed in full in Aventin *et al.*² and are summarised below:

1. Know and involve your target population and engage their gatekeepers in addressing contextual complexities:
 - i. systematic reviews
 - ii. primary research
 - iii. development/adaptation of film script, storyboard and interactive questions
 - iv. consultation
 - v. participation.
2. Know the behaviours you wish to target and model the process of change:
 - i. psychosocial theory
 - ii. characteristics of effective interventions
 - iii. logic modelling.
3. Look beyond development:
 - i. consider evaluation, implementations and knowledge transfer from the start.

Limitations

A recent systematic review of effective sexual health interventions¹⁹ indicated the importance of building connections with community-based sexual health services and providing longer-term programmes. The *If I Were Jack* intervention was unable to address such components owing to the strategy employed to

develop and test an existing IVD. Such issues and other evidence-based components could be addressed in future development work.

As the *If I Were Jack* intervention strongly emphasises the potential negative consequences that having a child might have on a teenager's current life or future goals, another potential limitation of the intervention is that it may have a possible negative impact on teenagers who have had, or are about to have, a child. It has the potential to reinforce or indeed instigate stigmatisation processes. Design features of the intervention aim to off-set this potential negative impact through the teacher training process, which emphasises the importance of reminding and discussing with pupils that the resource refers to UTP (i.e. a pregnancy that is unexpected and unwanted) rather than a teenage pregnancy in general, which for some young people can be a planned and positive experience. Pupils are also informed by the teachers and researchers involved that they can and should contact the school counsellor/pastoral care (PC) officer should they find any part of the intervention upsetting.

Conclusions

The *If I Were Jack* intervention is a unique, evidence-based, theory-informed intervention that to date has been found to be acceptable to statutory stakeholders, teachers, pupils and parents in diverse geographical and cultural settings (Ireland, NI and Australia). The intervention is based on existing evidence-based RSE programmes targeting UTP and includes key behaviour change techniques that are influential in changing sexual behaviour and incorporates sociological understandings of gender norms relating to pregnancy. The *If I Were Jack* intervention is the first to be documented in the scientific literature² that specifically addresses teenage males and UTP.

Although the MRC guidelines⁸⁹ suggest a very useful framework for conducting Phase I research, they provide little description of how this should proceed (relative to guidance provided on Phases II–IV). This effectively relegates the importance of this phase to considerations of summative evaluation, despite growing consensus that the development of conceptually based, acceptable interventions is of vital importance before proceeding to trial. This is compounded by a dearth of published literature reporting the development of complex interventions in practice. The result is an increased potential for misallocation of research labour and resources on what is already a costly and time-consuming process. More broadly, as the new mantra of knowledge translation spreads across the academic community there is ever more need to report intervention development processes and intervention components in detail for others seeking to bridge the gap between research and interventions. Reporting on these methodological processes has already directly inspired a research team to develop and evaluate a similar IVD-based educational resource on young people and marijuana use for British Columbia, Canada, entitled Cycles (University of British Columbia, Vancouver, BC, Canada).⁹⁵ Consequently, the model of intervention development reported in this report and elsewhere² is presented not as an ideal, but as an exemplar that other researchers might utilise, modify and improve.

Chapter 4 Developing and evaluating the questionnaire

Introduction

The study endeavoured to conduct a qualitative and quantitative validation of a questionnaire developed for the study to ensure its reliability and acceptability to participants. The questionnaire incorporated validated questions from the Sexual Health And Relationships (SHARE) questionnaires¹⁸ and items from a number of standardised measures to provide broad estimates of effect size and the feasibility and acceptability of the questions. The measures were chosen because the constructs they measure map closely to the theoretical framework underpinning the intervention (theory of planned behaviour; see *Chapter 3*) and they are widely used measures with robust reliability and validity (see *Appendix 6*). The questionnaire also incorporated a measure of intention to avoid UTP, developed as part of the research process (see *Feasibility study* below). A prior intention in relation to development was that the questionnaire should aim to take no longer than 30 minutes to complete, as this is the average length of RSE lessons in NI. Effort was made to ensure that the study team consulted with the sexual health and education expert members of the project Stakeholders Group and end users who are members of the Trial Steering Group (see *Chapter 1*) regarding the acceptability of the questions in the long version of the instrument. The structure of the chapter will describe the following stages in development and evaluation.

Pilot study

Rationale

A key outcome of this study was to pilot test the feasibility, usability and acceptability of providing demographic data and answering questions measuring the proposed primary and secondary outcomes of a future Phase III trial (see *Chapter 6*), that is, sexual behaviour data, including engagement in sexual intercourse, contraception use and diagnosis of STIs; data regarding knowledge, attitude, skills and intentions relating to avoiding UTP; and data on socioeconomic status (SES). The pilot study was not intended to assess the design and usability of the format of the questionnaire itself.

Methods

Unlike the finalised version of the questionnaire (for the feasibility study), the pilot version was of a basic format using the SurveyMonkey™ (Palo Alto, CA, USA) platform as the feasibility trial website was still in design.

To pilot test the questionnaire prior to the beginning of the feasibility trial, a school was approached that had been identified as willing to use the questionnaire, through prior liaison, with 50–60 of their Year 11 students (male and female, aged 14–15 years), who had proactively volunteered. In order to facilitate completing the questionnaire online, the Year 11 students were split into two groups across two different computer rooms and a researcher and a Learning for Life and Work (LLW) curriculum teacher (see *Appendix 7*) were present at all times in both groups. The session lasted for 1 hour. The data were analysed quantitatively by use of descriptive statistics and analysis of the reliability and spread of the scales.

Qualitative analysis was also made possible via focus group methodology. Focus group interviews are used extensively within social sciences to elicit information, perceptions, beliefs and attitudes. The group dynamic allows for a more natural conversational style rather than a traditional rigid interview technique. Researchers often use this technique to engage the end user in instrument design. Pupils who had completed the questionnaire were asked to participate in the focus group session regarding the acceptability and feasibility

of the questions. These interviews lasted for 25 minutes. The students gathered around in a circle and the discussion was audio-recorded to facilitate note taking at a later stage. To begin with, the researchers reminded the students of the purpose (i.e. to find out what they thought about the questionnaire and not to be afraid of giving their honest opinions). The researchers also went over some ground rules, following the Respect, Involvement, Confidentiality, Equality (RICE) rules below:

R: Respect for an individual's contributions, which we can demonstrate by listening to one another's views.

I: Involvement in the discussions and activities.

C: Confidentiality – we are not going to talk about our own personal/individual stories but we can talk about relationships in general.

E: Equality – we want to acknowledge that everyone's experience and opinions are equally valid.

The questions asked during the course of the cognitive interviews are listed below.

1. Would you prefer to complete the questionnaire on the computer or on paper?
2. What did you think about the length of the questionnaire?
3. What did you find useful or interesting about the questionnaire?
4. What did you find difficult or confusing about the questionnaire?
5. Is there anything that you think should be removed from the questionnaire?
6. When you talk about these issues with your friends what terms do you tend to use?
7. I have some specific terms that I wanted to check your understanding of. Ask what would that mean to you? Do you think there are some people your age who would not understand what it meant?

For invitation letters, information sheets and consent forms for schools, teachers, parents/guardians and pupils regarding questionnaire development, see *Appendix 2*. For the focus group topic guide, see *Appendix 3*.

Results

The participating school was a grant-maintained integrated co-educational secondary school (which did not go on to be involved in the feasibility trial). The school was located in an urban area and 17.8% of its students were eligible for free school meals. In total, 38 students (mean age of 14.72 years) agreed to take part (in two rooms containing 22 and 16 pupils, respectively), provided parental consent and completed the questionnaire.

Quantitative analyses

The estimated time taken to complete the questionnaire was 40 minutes; the actual time taken was around 25 minutes, including time taken to log in. The first section contained sociodemographic questions. The sample of respondents comprised 55% male and 45% female students and was split between 14- and 15-year-olds (26% and 68%, respectively). All students completed these questions, although two incorrectly inputted the date of the pilot study instead of their date of birth. Owing to this error, the online questionnaire was developed to bring up an error message if the year of birth does not equate to a Year 11 student. Sixteen students skipped the question that asked them to write in their postcode. As this information is important for a check to ensure that questionnaires can be correctly linked across the trial and potentially used for gathering multiple deprivation score, it was necessary to keep this in but it was accompanied with more explanation as to why this information was being collected. One question asked about the educational achievement of the respondent's mother and father (or guardian) and was broken down into six questions asking specifically about General Certificates of Secondary Education (GCSEs), Advanced levels (A levels), degrees, apprenticeships, diplomas or no qualifications. Five participants skipped these questions and 18 did not know the answer. It was therefore decided to incorporate these questions into a single item referring to highest achieved qualification.

Owing to limited variation in responses received to the categorical tick box responses for the question 'Whose responsibility is it to prevent unintended pregnancy?', it was decided to change the response format of the question to the following visual analogue scale (*Figure 3*), with the following instructions: put an X on the line below to show how much responsibility you think boys and girls should have. For example, if you think that girls have more responsibility than boys, put an X on the line closer to girl; if you think that boys have more responsibility than girls, put an X on the line closer to boy; if you think that boys and girls should have equal responsibility, put an X in the middle of the line.

Only 14% (five participants) of the sample said that they had experienced penetrative sex and only three answered the question regarding their age at which they first had sex, which was 15 years. When asked how many times they had had sex, two participants responded that they had had sex once; however, one participant said that they had had sex 30 times. It could be likely that they have been sexually active 30 times in the past but it could also be the case that this may have been an error and was perhaps meant to say 'three'. To minimise this type of error and therefore to ensure that we could correctly interpret the data, it was decided to use fixed-category responses rather than free responses.

As the pilot study sought to determine participants' level of comfort in answering potentially personal questions about a sensitive topic, the question 'how comfortable do you feel in answering these questions?' was added to the pilot questionnaire to assess this. Most participants felt comfortable answering all or most of the questions ($n = 18$), but some did report experiencing discomfort ($n = 7$).

Reliability and spread of pilot results

The decision to include or exclude scales or items was based on internal consistency (Cronbach's alpha), and the overall variability of the data produced (standard deviation). Those values > 0.70 were considered acceptable (*Table 1*). The internal consistency for the Sexual Stereotyping scale did not meet the threshold; this measure was included because it produces a high degree of variability in the data. This was replaced by the Male Role Attitude scale instead, which can be used by both sexes. The attitude items were excluded owing to their unacceptable levels of internal consistency and low degree of variability.

The knowledge items (*Table 2*) employed a true/false response format rendering a check on internal consistency inadvisable. However, closer examination of the individual items revealed that some were producing ceiling effects, indicating that the questions were too obvious. A decision was made to exclude items 2, 4, 9 and 10 and to retain all other items.

The Cost of Unintended Pregnancy scale had an acceptable level of internal consistency ($\alpha = 0.699$; see *Table 7*); however, on account of the three-point Likert scale, it produced very little variability in participant responses (*Table 3*). A decision was made to exclude the scale on this basis.

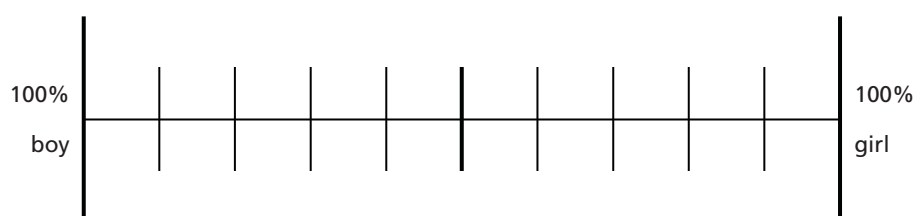


FIGURE 3 Whose responsibility is it to prevent unintended pregnancy? A visual analogue scale.

TABLE 1 Measures included or excluded on the basis of internal consistency and variance

Measurement scales or knowledge items	Cronbach's alpha	Number of items	Mean	Standard deviation
1. Sexual Self-Efficacy	0.922	13	110.8	11.7
2. Intentions to Avoid Teenage Pregnancy	0.869	16	127.4	18.0
3a. Comfort Communicating about Sex (boys)	0.812	6	84.0	25.7
3b. Comfort Communicating about Sex (girls)	0.721	6	88.2	23.0
4. Costs of Unintended Pregnancy	0.699	6	75.2	17.5
5. Sexual Stereotyping	0.611	11	59.7	22.8
6. Attitudes	0.364	4	56.5	4.4

TABLE 2 Frequencies and percentages of true/false responses for knowledge items

Knowledge items	True, n (%)	False, n (%)
1. Washing the vagina after penetrative sex will help to prevent pregnancy (false)	12 (31.6)	25 (65.8)
2. A girl <u>cannot</u> get pregnant the first time she has penetrative sex (false)	7 (18.4)	28 (73.7)
3. A girl <u>can</u> get pregnant if the boy withdraws his penis (pulls out) before ejaculation (coming) (true)	22 (57.9)	15 (39.5)
4. When a teenage boy and girl have a baby together, they will likely get married to each other eventually (false)	7 (18.4)	30 (78.9)
5. Contraception (when used correctly) provides as much protection against pregnancy as not having sex (false)	22 (57.9)	15 (39.5)
6. The rhythm method (only having sex during the few days before and after a woman's period) is as safe as using a condom in preventing pregnancy (false)	18 (47.4)	18 (47.4)
7. When teenagers have penetrative sex <u>for the first time</u> , the majority of them use condoms (false)	14 (36.8)	22 (57.9)
8. Teenage males can seek advice from pregnancy counsellors (true)	20 (52.6)	16 (42.1)
9. An advantage of using condoms is that they help prevent sexually transmitted diseases (true)	33 (86.8)	2 (5.3)
10. An advantage of using condoms is that they can be bought in shops and chemists by either boys or girls (true)	35 (92.1)	1 (2.6)
11. More than half of all teenagers in Northern Ireland have had penetrative sex by the time they are 16 (false)	31 (81.6)	5 (13.2)

TABLE 3 Costs of Unintended Pregnancy scale

Costs of unintended pregnancy ($\alpha = 0.699$)	Mean	Standard deviation
1. Teenagers avoid pregnancy because their parents would not approve	1.80	0.871
2. Teenagers avoid pregnancy because they are not ready to be a parent	2.46	0.373
3. Teenagers avoid pregnancy because having to decide whether to keep the baby or not might be a very difficult decision	2.31	0.398
4. Teenagers avoid pregnancy because having a baby might really change their life	2.51	0.375
5. Teenagers avoid pregnancy because it might mess up their future plans for college, school or a career	2.51	0.316
6. Teenagers avoid pregnancy because their friends would not approve	1.32	0.771

Qualitative analysis

All 38 pupils who answered the questionnaire participated. The questions asked during the course of the cognitive interviews are listed below, along with the responses given by the students.

1. Would you prefer to complete the questionnaire on the computer or on paper?

In this pilot, all pupils completed the questionnaire using the online SurveyMonkey™ format. However, they were asked if they would prefer to do this on paper or computer. There was general agreement with the students that they would prefer to do this online, that it would be more confidential.

because once you click the button it is away

2. What did you think about the length of the questionnaire?

Most said it was too long. Others said:

'too much reading'; 'frustrating'; 'it was all right'; 'too personal'; 'I thought it was all right'; 'very detailed'; 'too many details in some parts'.

One student noted that:

it was shorter than the other one we did.

3. What did you find useful or interesting about the questionnaire?

Responses to this varied:

'not really'; 'it was all interesting'; 'it was useful'.

One student felt that the questionnaire would help give teenagers the opportunity to think through issues:

it's a good mind set for teenagers – gives them an idea of what sex is actually like and what pregnancy can do. It can ruin your life if you want to have a scholarship or go to college or something like that.

As this was a pilot and not part of the trial, students were given an answer sheet to the true and false knowledge questions after they had finished. They really liked getting this information, although this would not be offered to students in the main trial.

4. What did you find difficult or confusing about the questionnaire?

The length of the questionnaire was mentioned as a disadvantage:

just the number of questions that kept coming up and up after every single question.

There was also confusion over the difference between likely and somewhat likely. Other comments made included:

'some didn't make sense'; 'it was weird'.

It was not possible to clarify the meaning of these terms in either case but the researcher present thought that they were trying to say that they could not understand why some of the questions were part of a questionnaire about UTP.

5. Is there anything you think should be removed from the questionnaire?

Both groups agreed that asking for the postcode should be removed and queried why it was in there.

I don't like giving my postcode.

Some pupils thought that the question 'have you ever had sex' should be removed. One pupil said this was too personal; however, this point of view did not garner much agreement from others. Another student felt that the question relating to family finance was also too personal to ask.

I didn't understand why there were questions about your financial circumstances. Just the financial stuff is a bit personal.

Some said that the set up with everyone sitting so close made them feel uncomfortable and others said that they did not mind. They suggested that we could make it more private by asking them to do it at home (some said they would not feel comfortable doing this), one suggested a sheet of paper, talk to each pupil privately, interview them (others disagreed with this); do it on your phone.

6. When you talk about these issues with your friends what terms do you tend to use?

It was reported that they would not use the terminology in the questionnaire when talking with friends. The discussion then moved to a discussion of what terms they did not understand, which were stated to be 'legal highs', 'sexual advance' and 'rubber Johnny'.

7. I have some specific terms that I wanted to check your understanding of. Ask what would that mean to you? Do you think there are some people your age who would not understand what it meant?

Feedback on participants understanding of key terms used is detailed in *Table 4*.

Observations made during questionnaire completion

Although there were two groups completing the questionnaire independently in different rooms, the two researchers administering the questionnaire observed similar issues. The major difficulty observed by both researchers was that friends sat side by side and many openly and audibly discussed their answers and the meanings of words/questions/response sets. This was even more of an issue in the group that had the least personal space. To combat this the possibility to play music via the internet to keep the students focused and minimise the opportunity for discussion was examined. Ultimately this would not be possible, owing to issues such as the selection of music, the availability of headphones in schools and the ability of the software. Emphasis was placed at the beginning of the questionnaire that this questionnaire addresses private and sensitive issues and that respondents should remember to respect each other's privacy when completing the questionnaire and not to discuss their answers. Other issues that were noted during the observations were:

- One female, in reference to the Intentions scale, said that she could not answer the questions because she felt that they were too personal. The researcher reminded her and the rest of the group that they could skip any questions they were uncomfortable answering. A decision was made to emphasise this more clearly in writing on the questionnaire and in the verbal introduction.
- Some queried the Likert-scale responses on the Intentions scale:

What's the difference between likely and somewhat likely?

- Other questions or comments included:

'what is penetrative sex?'; 'what is a legal high?'; 'what is contraception?'; 'I don't remember my post code'.

TABLE 4 Participants' understanding of key terms used

Phrase for clarification	Student response to phrase	Altered phrase
'Future sexual encounter'	No problem	–
'Resist peer influence'	No problem	–
'In a relationship'	No problem	–
'Sexual advance'	Did not understand	Added a definition: can be used to describe an attempt by one person to gain sexual favour with another (also called 'come on to' or 'pull')
'A sexual encounter'	No problem	–
'Feeling obliged to have sex'	Did not understand	Changed to 'feeling you have to'
'Control your sex urges'	No problem	–
'Peers'	No problem	–
'Most women cannot be trusted'	No problem	–
'dating relationship'	Outdated	Changed to 'boyfriend/girlfriend'
'manipulate'	Did not understand	Added a definition: to control or influence (a person or situation) cleverly or dishonestly
'highly regarded'	Did not understand	Change
'easy/sexually easy'	Had some problems	Added a definition: can mean someone who agrees to have sexual intercourse with others without difficulty
'multiple sexual partners'	No problem	–
'sexually active'	Did not understand	Added a definition: can be used to describe a person who participates in sexual intercourse
'sexual exploits'	Did not understand	Added a definition: the people you have had sexual intercourse with in the past
'sexuality'	Had some problems	Added a definition: can be used to describe a person's sexuality or preference (e.g. whether you are sexually attracted to males, females, both males and females, or have never been attracted to anyone)
'Other drugs'	Had difficulties thinking about other types of drugs	Added: 'e.g. ecstasy, magic mushrooms, LSD, cocaine, heroin'

- One male said that he did not have a father so should he put 'not sure' in response to the paternal education question. It was decided that the questionnaire employed in the feasibility trial should include a 'not applicable' option.

Summary of changes made to questionnaire for feasibility study

In conclusion, the Year 11 students who assisted with the pilot development stage of the questionnaire were mostly positive about their experiences in completing the questionnaire. Feedback on their understanding of key terms used was critical to ensure that future participants can understand what is being asked and also to enable reliable estimates of effects. A number of changes were made to the questionnaire in light of this work, which are summarised below.

- changes made to terminology used
- 'hover over' definitions used on terms on the online questionnaire and a separate definitions page on the paper version of the questionnaire
- response format from one questionnaire changed to a visual analogue scale
- more description about a Likert scale and how to answer them

- removed Cost of Unintended Pregnancy scale
- the knowledge items two, four, nine and 10 were removed
- changed 'How many times have you had sex?' question from free response to fixed-category tick boxes
- included 'not applicable' option to question on paternal and maternal education?
- greater explanation of why we are asking for postcodes
- inserted reminders in the online questionnaire if any items are left blank unintentionally
- validity checks for date of birth inserted into online questionnaire
- explained why the questionnaire contains questions relating to parental education and finances
- broke up how longer scales are displayed – no more than six questions per page
- added progress bar to online version.

Feasibility study

Further exploration and analyses of how well the questionnaire performed after baseline data collection, after follow-up 1 (second data collection wave) and post trial after follow-up 2 (third wave of data collection) were conducted. The following sections detail this, in addition to any further proposed changes thought necessary to bring forward to a main trial.

Rationale

The aim was to further refine the survey instruments by assessing their acceptability and usability among the pupils now completing them within the setting of the feasibility study.

Methods

An electronic version of the questionnaire was developed post pilot and offered to the schools as an alternative to the use of paper-based questionnaires.

The data were analysed quantitatively following baseline data collection, by use of descriptive statistics and analysis of the reliability and spread of the scales. The research team also made minor amendments to the survey instruments to aid user understanding after each data collection wave; these changes were based on analysis of responses and qualitative experiences of watching the pupils complete them.

As with the pilot study, qualitative analysis was also made possible via focus group methodology. This was conducted post trial. Two separate focus groups were conducted within two of the control group schools. The focus groups were audio-recorded to ease transcription and lasted no longer than 45 minutes. Soft drinks and snacks were provided and the interviewer tried to create a relaxed atmosphere to facilitate a discussion in which everyone had a voice. The focus groups were timed to coincide with the end of data collection for the feasibility trial and occurred either directly after data collection or within a few days of this. This timing ensured that issues the participants may have had and the survey instrument itself would be fresh in their minds. Although they were already familiar, sample questionnaires were given out to all participants so that they could examine it in detail.

Participants were given an overview of what a focus group is as well as a topic guide (see *Appendix 3*). They were reminded that although they would be discussing the questionnaire, for example, whether the questions were easy or difficult, they would not be asked to discuss their own personal answers. For relevant invitation letters, information sheets and consent forms for schools, teachers, parents/guardians and pupils, see *Appendix 2*.

The focus group schedule (see *Appendix 3*) was divided into five topics: questionnaire instructions, questionnaire design, terminology used, individual questions and other issues.

Results

Quantitative analysis

Baseline data collection was conducted during December and November 2014 in eight schools with 831 pupils (mean age 14.45 years) completing the questionnaire across the eight participating schools. Three of the eight schools elected to use the electronic questionnaire at baseline data collection. The paper version of the questionnaire only was available for use at follow-up 1 and 2 data collection owing to technical software problems.

Analysis of demographic variables

Table 5 details the questions in the 'about yourself' and 'your family' sections. Within this section we tried to assess social class in a variety of ways. A surprisingly small percentage of pupils aspired to attend university or college upon leaving formal schooling, suggesting that the wording of this question might require amendment. The majority of girls and boys categorised themselves as heterosexual. There was a range of living arrangements reported and a wide range of responses to respondents families' financial situation, although 'average' was the most common answer.

Analysis of primary and secondary outcomes

Sixty pupils (7%) surveyed reported that they had had sex and the average age at which they had sex for the first time was 13.7 years in the intervention group and 14 years in the control group. In the 'Age First Time' question one pupil entered 20 and another entered 21. As these are impossible values given the age of the pupils filling in the questionnaire, they were excluded from the summary calculations for this question. Of those who reported ever having sex, the most common number of partners was one; however, 42% reported having had more than one partner. A complete breakdown of these responses can be viewed in Table 6.

Table 7 shows the responses to the contraception questions. Fewer than half of those participants who reported sexual activity (either in the intervention or control group) stated that they always used contraception (48%). Twenty-two pupils reported that they had been unprotected in the last sexual encounter they had had. They reported using a range of contraception types, the most common of which was condoms. Twenty-six (45%) reported that they had sex without using a condom at least once in the past 6 months.

Table 8 lists the responses to questions regarding how easy or difficult participants would find accessing and using condoms. This question was asked to the entire sample. The majority of respondents felt that they would find it easy to suggest using condoms, but were not sure about how easily they would obtain condoms and how to use them correctly. However, these questions had a high rate of missing data (78 respondents either skipped or missed this question). This may be due to the fact that these questions were placed at the end of the questionnaire and therefore may have been missed due to time issues. Alternatively, respondents may have missed the fact that they were eligible to answer these questions, as they came directly after the sexual behaviour and pregnancy questions, which involved skipping instructions for those ineligible to complete them.

Responses to the alcohol and drug questions are provided in Table 9. In total, 419 (50%) pupils admitted to drinking alcohol and 54 (6.5%) admitted to having used drugs. Sixty-eight pupils (representing almost 20% of our sample) reported being drunk at least two to three times a month over the previous 6-month period.

Five questions were asked regarding reasons for delaying sex over the past 6 months, and responses are shown in Table 10. The majority of delayed sex was not due to contraception availability or alcohol or drug usage but rather to values. Many pupils felt that they should wait until they are older ($n = 390$) or that their parents would not approve ($n = 291$). Responses were mixed about whether sex had been delayed due to not having the correct partner, with slightly more pupils saying that this was not a consideration in delaying sex. Almost 300 pupils skipped these questions entirely. Similar to the issue reported above in the condom questions, this question had a high rate of missing data. This may be due to the fact that these questions were placed at the end of the questionnaire and therefore may have been missed as a result of time issues. Alternatively, respondents may have missed the fact that they were eligible to answer these questions, as they came directly after the sexual behaviour and pregnancy questions, which involved skipping instructions for those ineligible to complete them.

TABLE 5 Questions in the 'About yourself' and 'Your family' sections

Survey questions	Intervention	Control
Future aspirations, n (%)		
At college/uni full-time	63 (15.1)	46 (11.4)
At college/uni and working part-time	32 (7.7)	54 (13.4)
Working full-time	186 (44.7)	180 (44.7)
Working part-time	106 (25.5)	90 (22.3)
On a training scheme	15 (3.6)	19 (4.7)
Unemployed	4 (1)	1 (0.3)
Other	10 (2.4)	13 (3.2)
Sexuality, n (%)		
<i>Female</i>		
I have never felt sexually attracted to anyone	32 (18.3)	24 (12.1)
Only to males, and never to females	132 (75.4)	165 (82.9)
More often to males and at least once to a female	9 (5.1)	8 (4.0)
About equally often to females and to males	2 (1.1)	2 (1.0)
More often to females and at least once to a male	–	–
Only to females, never to males	–	–
<i>Male</i>		
I have never felt sexually attracted to anyone	13 (5.9)	6 (3.0)
Only to males, and never to females	1 (0.5)	1 (0.5)
More often to males and at least once to a female	–	2 (1.0)
About equally often to females and to males	1 (0.5)	4 (2.0)
More often to females and at least once to a male	1 (0.5)	3 (1.5)
Only to females, never to males	204 (92.7)	184 (92.0)
Live with, n (%)		
Both parents in same household	272 (65.2)	297 (72.4)
Mother only	81 (19.4)	65 (15.9)
Father only	8 (1.9)	7 (1.7)
Mother and partner or stepfather	30 (7.2)	28 (6.8)
Father and partner or stepmother	9 (2.2)	2 (0.5)
Grandparents only	2 (0.5)	1 (0.2)
Foster care	1 (0.2)	1 (0.2)
Others	14 (3.4)	9 (2.2)
Well off, n (%)		
Not at all well off	2 (0.48)	2 (0.5)
Not very well off	11 (2.7)	30 (7.4)
Average	198 (47.7)	189 (46.9)
Well off	147 (45.4)	140 (34.7)
Very well off	35 (8.4)	18 (4.5)
I do not know	22 (5.3)	24 (6.0)

TABLE 6 Responses to sexual behaviour questions

Survey questions	Intervention	Control
<i>Ever had sex, n (%)</i>		
Yes	35 (8.5)	25 (6.4)
No	376 (91.5)	367 (93.6)
Age first time	13.7 (0.184) <i>n</i> = 34	14 (0.096) <i>n</i> = 20
<i>How many people have you ever had sex with, n (%)</i>		
One	20 (58.8)	13 (54.2)
Between 2 and 5	7 (20.6)	7 (29.2)
Between 6 and 10	4 (11.8)	4 (16.7)
More than 10	3 (8.8)	–
<i>Number of times had sex in past 6 months, n (%)</i>		
Once	17 (53.1)	5 (22.7)
Between 2 and 5 times	11 (34.4)	7 (31.8)
Between 6 and 10 times	2 (6.3)	5 (22.7)
Between 11 and 20 times	–	1 (4.6)
More than 20 times	2 (6.3)	4 (18.2)
<i>When last had sex, n (%)</i>		
< week ago	5 (14.3)	7 (29.2)
> week ago but < month ago	9 (25.7)	7 (29.2)
1–6 months ago	16 (45.7)	7 (29.2)
> 6 months ago	5 (14.3)	3 (12.5)
<i>Number of sexual partners in past 6 months (girls), n (%)</i>		
One	5 (71.4)	6 (85.7)
Between 2 and 5	2 (28.6)	1 (14.3)
Between 6 and 10	–	–
More than 10	–	–
<i>Number of sexual partners in last 6 months (boys), n (%)</i>		
One	12 (60.0)	9 (69.2)
Between 2 and 5	6 (30.0)	2 (15.4)
Between 6 and 10	–	2 (15.4)
More than 10	2 (10.0)	–
<i>Had sex when you did not want to in past 6 months, n (%)</i>		
Yes	7 (21.9)	7 (28.0)
No	25 (78.1)	18 (72.0)
<i>Had sex when you did not want to in past 6 months (girls), n (%)</i>		
Yes	1 (11.1)	–
No	8 (88.9)	7 (100)
<i>Had sex when you did not want to in past 6 months (boys), n (%)</i>		
Yes	6 (26.1)	7 (38.9)
No	17 (73.9)	11 (61.1)

TABLE 7 Responses to usage of contraception questions

Survey questions	Intervention	Control
<i>How often has sex been protected, n (%)</i>		
Never	5 (14.7)	3 (13)
Not very often	4 (11.8)	4 (17.4)
About half the time	3 (8.8)	–
Most of the time	3 (8.8)	6 (26.1)
Always	19 (55.9)	10 (43.5)
<i>Contraception used the last time you had sex, n (%)</i>		
None for me, do not know about partner	8 (22.9)	3 (12.0)
None for either of us	5 (14.3)	6 (24.0)
Yes	22 (62.9)	16 (64.0)
<i>Type of contraception used the last time you had sex^a</i>		
Pill, patch or vaginal ring	5	5
Condoms	19	14
Emergency contraceptive pill	2	1
Injection	1	–
Implant	–	–
Withdrawal method	2	–
Intrauterine device	–	–
Diaphragm/cap/spermicide	–	–
Natural family planning	–	1
Do not know name	–	–
Other	1	–
<i>Number of times you had sex without a condom in past 6 months, n (%)</i>		
Never	19 (57.6)	13 (52.0)
Once	4 (12.1)	5 (20.0)
Between 2 and 5 times	7 (21.2)	4 (16.0)
Between 6 and 10 times	2 (6.1)	2 (8.0)
Between 11 and 20 times	1 (3.0)	–
> 20 times	–	1 (4.0)
^a Percentages are not provided here because the numbers are very small.		

TABLE 8 Responses to ease of accessing and using condoms

Survey questions	Intervention	Control
<i>Ease of getting condoms, n (%)</i>		
Very easy	68 (18.0)	54 (14.4)
Easy	85 (22.5)	77 (20.5)
Not sure	144 (38.1)	156 (41.6)
Difficult	48 (12.7)	51 (13.6)
Very difficult	33 (8.7)	37 (9.9)
<i>Ease of suggesting condoms, n (%)</i>		
Very easy	75 (20.0)	69 (18.7)
Easy	134 (35.6)	133 (36.0)
Not sure	133 (35.4)	118 (32.0)
Difficult	21 (5.6)	29 (7.9)
Very difficult	13 (3.5)	20 (5.4)
<i>Use a condom properly, n (%)</i>		
Very easy	88 (23.4)	59 (16.1%)
Easy	102 (27.1)	124 (33.9)
Not sure	155 (41.2)	151 (41.3)
Difficult	17 (4.5)	15 (4.1)
Very difficult	14 (3.7)	17 (4.6)

TABLE 9 Responses to questions in the alcohol and drugs section

Survey questions	Intervention	Control
<i>Ever drunk alcohol, n (%)</i>		
Yes	239 (57.2)	180 (44.0)
No	179 (42.8)	229 (56.0)
<i>How often have you got drunk in past 6 months, n (%)</i>		
Never	111 (46.6)	100 (55.9)
< once a month	74 (31.1)	65 (36.3)
2–3 times a month	31 (13.0)	7 (3.9)
Once a week	16 (6.7)	6 (3.4)
> once a week	6 (2.5)	1 (0.6)
<i>Ever taken drugs, n (%)</i>		
Yes	33 (7.9)	21 (5.2)
No	386 (92.1)	383 (94.8)

TABLE 10 Responses to delaying sex questions

Survey questions	Intervention	Control
<i>Delay sex because of no contraception, n (%)</i>		
Yes	63 (24.1)	55 (20.0)
No	198 (75.9)	220 (80.0)
<i>Delay sex because parents would not approve, n (%)</i>		
Yes	151 (55.3)	140 (49.5)
No	122 (44.7)	143 (50.5)
<i>Delay sex because under influence of alcohol/drugs, n (%)</i>		
Yes	28 (10.6)	27 (9.9)
No	237 (89.4)	247 (90.2)
<i>Delay sex because believe you should be older, n (%)</i>		
Yes	198 (67.4)	192 (62.5)
No	96 (32.7)	115 (37.5)
<i>Delay sex because was not with right partner, n (%)</i>		
Yes	112 (43.8)	96 (34.5)
No	144 (56.3)	182 (65.5)

Table 11 contains information about the pregnancy-related questions. One boy in the sample reported that he had got a girl pregnant; eight others reported that they did not know. One girl in the sample reported that she had been pregnant. Both pregnancies had occurred within the previous 12 months and one of these was still in the pregnancy stage; the other pregnancy outcome was not reported. The female respondent admitted that she had not intended to get pregnant, whereas the male respondent said that he had intended to get his partner pregnant.

Visual analogue scale

A small percentage of respondents did not answer this question (5.2%). The majority of participants placed the responsibility on boys to prevent UTP in the 26–50% range (Table 12), although there was a spread of answers across all the possible quartiles. Based on this we did not make any amendments to the visual analogue scale for the first follow-up.

Comfort completing the questionnaire

The majority of participants stated that they felt comfortable in answering most of all the questions in this questionnaire (80%, $n = 608$). A small number of participants (4%, $n = 27$) stated that they were uncomfortable in answering all of the questions asked. Again there was a high percentage of missing data for this question, potentially as a result of it being the last question.

Scale reliability and validity

Cronbach's alpha is calculated as a measure of internal consistency/reliability for all scales. Overall, the reliability of the measures was satisfactory (Table 13).

The Sexual Self-Efficacy scale, Male Role Attitudes scale and Sexual Socialisation Peer scale had high internal consistency (Cronbach's alpha in excess of 0.7), Family Connectedness, Comfort Communicating about Pregnancy, Comfort Communicating about Contraception, Sexual Socialisation Total and the Sexual Socialisation Parent scales had satisfactory internal consistency (Cronbach's alpha: 0.526–0.699). Overall, there was a high proportion of missing data for nearly all of the scales.

TABLE 11 Responses to questions relating to pregnancy

Questions and responses	Intervention	Control
[Boys] Ever got a girl pregnant, n (%)		
Yes	–	1 (5.9)
No	20 (76.9)	14 (82.4)
Do not know	6 (23.1)	2 (11.8)
[Girls] Ever been pregnant, n (%)		
Yes	1 (12.5)	–
No	7 (87.5)	6 (100.0)
Do not know	–	–
How many months ago did you/she get pregnant, n		
Less than 1 month ago	–	1
Between 2 and 5 months ago	–	–
Between 6 and 9 months ago	–	–
Between 10 and 12 months ago	1	–
More than 1 year ago	–	–
Do not know	–	–
What happened with pregnancy, n		
Still pregnant	–	1
Miscarriage	–	–
An abortion	–	–
A baby	–	–
I do not know	–	–
Intended pregnancy (girls), n		
I intended to get pregnant	–	–
My intentions kept changing	–	–
I did not intend to get pregnant	1	–
Intended pregnancy (boys), n		
I intended for my partner to get pregnant	–	1
My intentions kept changing	–	–
I did not intend for my partner to get pregnant	–	–

TABLE 12 Responsibility to prevent unintended pregnancy percentage attributed to boys

Quartiles	Intervention (%)	Control (%)	Total (%)
0–25%	2.4	2.2	2.3
26–50%	78.1	78.4	78.2
51–75%	12.0	11.5	11.8
76–100%	3.2	2.0	2.5
Skipped question	4.3	6.1	5.2
Total	100.0	100.0	100.0

TABLE 13 Scale descriptives and reliability

Scale	Completed, <i>n</i>	Mean	SD	Min.	Max.	Cronbach's Alpha
Family Connectedness	813					0.526
Intervention	409	15.2	0.123	4	20	
Control	404	15	0.094	7	20	
Comfort Communicating about Pregnancy	756					0.576
Intervention	385	5.4	0.153	2	8	
Control	371	5.4	0.107	2	8	
Comfort Communicating about Contraception	706					0.699
Intervention	349	8.3	0.087	3	12	
Control	357	8.4	0.131	3	12	
Sexual Self-Efficacy	557					0.876
Intervention	280	3	0.198	0	5	
Control	277	3.1	0.123	0	5	
Male Role Attitudes	682					0.729
Intervention	341	18.9	0.836	8	32	
Control	341	19.4	0.244	8	32	
Sexual Socialisation Total	718					0.568
Intervention	328	49.7	1.080	28	82	
Control	336	49.6	0.538	28	71	
Sexual Socialisation Peer	704					0.748
Intervention	352	31.4	0.612	14	59	
Control	352	31.2	0.300	13	49	
Sexual Socialisation Parent	706					0.596
Intervention	358	18.4	0.622	9	32	
Control	348	18.4	0.264	9	29	

Max., maximum; min., minimum; SD, standard deviation.

There are seven items assessing knowledge. The overall knowledge scores were roughly equal for both groups ($n = 4.7$ intervention group; $n = 4.5$ control group). The knowledge items (*Table 14*) employed a true/false response format, rendering a check on internal consistency inadvisable. The questions highlighted in bold in *Table 14* are those for which the majority of respondents gave the incorrect answer. These results suggested that there were some items that could be dropped from the main trial questionnaire, such as the item 'washing the vagina after penetrative sex will help to prevent pregnancy', for which most respondents selected the correct answer.

Intentions to Avoid Teenage Unintended Pregnancy scale

An Intentions to Avoid Teenage Unintended Pregnancy scale (TUPS) was developed for inclusion in the questionnaire (see Pupil Questionnaire in *Appendix 3*). A related publication is in preparation for submission and is detailed in publications associated with the report in the *Acknowledgements* section. Each item in the TUPS was preceded by the stem 'when thinking about future sexual encounters how likely is it that you would . . .'. All items were summed to produce a total score, which could range from 15 to 75, with higher scores indicating greater intentions to avoid UTP. Existing intention measures focused mainly on retrospective

TABLE 14 Frequencies and percentages of true/false responses for knowledge items

Knowledge item	True, n (%)	False, n (%)
Washing the vagina after penetrative sex will help to prevent pregnancy (false)	50 (6)	522 (63)
A girl <u>can</u> get pregnant if the boy withdraws his penis (pulls out) before ejaculation (coming) (true)	348 (42)	279 (34)
Contraception (when used correctly) provides as much protection against pregnancy as not having sex (false)	261 (31)	349 (42)
The rhythm method (only having sex during the few days before and after a woman's period) is as safe as using a condom in preventing pregnancy (false)	83 (10)	363 (47)
When teenagers have penetrative sex <u>for the first time</u>, the majority of them use condoms (false)	340 (41)	201 (24)
Teenage males can seek advice from pregnancy counsellors (true)	393 (47)	101 (12)
More than half of all teenagers in Northern Ireland have had penetrative sex by the time they are 16 (false)	382 (46)	132 (16)
Bold indicates the questions to which the majority of respondents gave the incorrect answer.		

reports of women, whereas this scale was designed to be prospective, including both men and women. Content validity was established through basing scale items on the empirical literature and then testing these in the pilot study. After completing the 15 items of the TUPS all students took part in a discussion about the scale. Some expressed confusion over the terms used in the Likert scale (e.g. what was the difference between somewhat likely and extremely likely), while others felt that some of the questions were too personal. The five-point Likert scale comprised extremely unlikely = one, somewhat unlikely = two, unsure = three, somewhat likely = four, and extremely likely = five. The spread of descriptive statistics showed that the majority of pupils were able to use the scale in a sensible manner; therefore, no changes to the scale were deemed necessary. The subject matter of the scale means that several items seek information of a personal nature. All students were informed that if they felt uncomfortable answering any questions they could skip them. As this is ultimately a matter of personal opinion, no further action was taken. During the feasibility study construct validity of the TUPS was established by means of principal components analysis, which revealed three factors (contraceptive use, child–parent communication and controlling the timing of sex), spread across 12 items. Internal consistency of the 15-item tool as measured by Cronbach's alpha was 0.798. The TUPS is a potentially useful measure of adolescents' intentions to avoid UTP that has been psychometrically validated, and we would continue to incorporate its use moving forward to a full trial. The scale could be especially useful in assessing the impact of future interventions designed to prevent UTP in this population.

Analysis of socioeconomic status variables

Socioeconomic status was measured in the study using six different variables in order to determine the best measurement to use for a future Phase III trial. The different measurements used were postcode (also used as a back-up method to match questionnaires across the three time points), receipt of free school meals, mother's highest level of education, father's highest level of education, how well off the family is perceived to be and future aspirations. *Table 15* shows the breakdown of the missing data and 'don't know' responses for each variable across all three time points.

Table 15 demonstrates that two of the SES measures (mother's and father's educational level) had unacceptably high levels of non-response. Those measures were not repeated in either of the follow-ups. Highest level of parental education is a commonly used proxy measure of SES in the literature, although based on the results from this feasibility study this measure would not be selected for use in the full trial. The other measures had smaller, more stable, levels of missing data across all three time points (ranging

TABLE 15 Missing data and 'don't know' responses for the SES variables

Measure	Baseline, n (%)	Follow-up 1, n (%)	Follow-up 2, n (%)
Postcode	28 (3)		
Do you receive free school meals?	33 (4)	47 (7)	10 (1)
What is your mother's highest level of education?	302 (36)	^a	^a
What is your father's highest level of education?	304 (37)	^a	^a
How well off is your family?	62 (7)	26 (4)	18 (2)
What are your future aspirations?	12 (1)	12 (2)	19 (2)
^a Question not asked.			

from 1% to 7%). The question 'How well off is your family?' did present some challenges to understanding (see *Chapter 2*); however, as the study progressed we modified the explanation for this question and consequently reduced the level of non-response down to 2% (from 7%). As such, the research team have increased confidence in the quality of responses received on this question. As SES is difficult to measure, prior to going forward to a future Phase III trial the research team would endeavour to conduct more qualitative research with a young people's advisory group and a review of the literature to ascertain those measures that we should continue to use.

Summary of changes made to questionnaire for first follow-up data collection (5 months after baseline data collection)

1. Added 'If there are any questions you do not understand, look at the list of definitions at the end of the questionnaire but please ask us if you need any help' to the instructions.
2. Questions 4 (What is your ethnic background?), 5 (How religious do you think you are?) and 6 (What religion where you brought up with?) removed from the baseline questionnaire.
3. Question 7: changed to include '(By this we mean how well off your family is in terms of money)'.
4. Question 11: changed from 'Have you ever drunk alcohol?' to 'Have you ever taken an alcoholic drink (not just a taste or a sip)?'.
5. Question 20: certain questions within changed from 'For girls/boys only' to 'If you are a girl/boy'.
6. Question 21: changed font size and highlighted important instructions.
7. Question 22: removed 'This section concerns beliefs about being a man.' From the description.
8. Question 23: changed 'your degree of agreement/disagreement with' to 'how you feel about'.
9. Question 43: moved to the next page.
10. Moved Thank you message up to above Question 46.
11. Question 46: removed lines and shortened box size.
12. Added definitions page.

Summary of changes made to questionnaire for second follow-up data collection (9 months after baseline data collection)

1. Added NIHR logo.
2. Removed Participant identification number (ID) and Date completed from front cover.
3. Added 'If there are any questions you do not understand, look at the list of definitions at the end of the questionnaire but please ask us if you need any help' to the instructions.
4. Questions 4 (What is your ethnic background?), 5 (How religious do you think you are?) and 6 (What religion where you brought up with?) removed from the follow-up questionnaire.
5. Question 7: changed to include '(By this we mean how well off your family is in terms of money)'.

6. Question 11: changed from 'Have you ever drunk alcohol?' to 'Have you ever taken an alcoholic drink (not just a taste or a sip)?'.
7. Question 20: certain questions within changed from 'For girls/boys only' to 'If you are a girl/boy' and added 'Boys & Girls' to other questions.
8. Question 21: changed font size and highlighted important instructions.
9. Question 22: removed 'This section concerns beliefs about being a man' from the description.
10. Question 28: added additional option 'not since June 2015' as the first option.
11. Question 43: moved to the next page.
12. Moved Thank you message up to above Question 46.
13. Question 46: removed lines and shortened box size.
14. Added definitions page.
15. Changed all 'Go to Q...' references to 'Go to Question...'.
16. Changed word search.

Qualitative data analysis

In total, 12 pupils participated (six in each group), each of whom had responded at least twice to the paper version of the questionnaire. The groups comprised both male ($n = 4$) and female pupils ($n = 8$).

Questionnaire instructions

Both focus groups began by reading the first page of the questionnaire, which contained the instructions to aid completion. The clarity of the instructions was then discussed and anything that had been missed out that really should be stated on this page was considered. Both groups felt that, overall, the instructions contained the right amount of information and were clear, with the exception of one statement. The troubling statement was 'Don't spend much time on any one question; make a choice and move to the next'. It was clear from the discussion that this was confusing and they felt that a statement like 'if you are stuck on a question, move on to the next question and you can come back to that one later' would be more clear. They felt that the instructions were reassuring, saying 'that you don't have to answer all of them if you don't want to'. They also liked the pointer to the list of definitions that is at the back of the questionnaire and suggested that it should be highlighted more and perhaps put at the top of the page so that everyone will notice it. One participant suggested that there should be a pointer to the definitions at the top of every page such as, 'if you have trouble with some of the definitions then see the definitions page at the back'.

One of the groups highlighted the fact that they did not actually read the instructions when they were completing the questionnaire, instead skipping on to the first question and that they thought that most others were the same. One stated 'I didn't even know they were there'. Someone else said 'I knew they were there – but it's probably only for people completing it first time'. Another felt that 'you just really get on with the questions' but that it was good to have the instructions just in case.

This highlights that the instructions need to be more visible and integrated within the questionnaire.

Questionnaire design

The focus groups then discussed the design and visual appeal of the questionnaire. They felt that printing the questionnaire in colour as opposed to black and white would not have any specific advantages and that it was fine the way it was. One person felt that it was off-putting at first because 'it just looked like there was a lot but then you fly through it'. They felt like there should be more clear space as the sections were 'a bit close together'.

Font type and size were deemed to be fine. The shading of alternative question lines was complimented as it 'helps keep you on track with the questions'.

One of the focus groups noted a design element that impacted on the privacy of participants. They had noticed that if you reported having previously had sex that the last section contained a large number of

questions that needed to be completed. Those reporting no sex did not have to complete this section. Therefore, this meant that you could work out who in the class had had sex.

One thing that maybe would be like embarrassing for someone who has had sex and doesn't want their friends to know and then they are at it for an extra 10 minutes compared to everyone else.

This was seen as being obvious to spot, 'It is really easy to see you can just look around you'.

In order to combat this the group discussed randomising the sections so that it would not be as obvious or add in dummy questions to keep everyone roughly to the same time. Overall, there is a need to space out the questionnaire and potentially consider randomising the questions within it to ensure privacy.

Terminology used

The conversations then moved on to discussing the specific terminology used within the questionnaire. To aid understanding and to minimise any potential embarrassment at having to ask questions because they may be 'too embarrassing to ask' or 'they [classmates] might mock you for not knowing it', a definitions list was provided along with the questionnaire after the initial baseline data collection. In the second round of data collection this definition list was provided as a separate sheet and in the final data collection round this was provided within the questionnaire, on the back page. Some of the focus group participants admitted that they did not 'even know they were there', whereas some did use this page and found it useful. Those who did not notice the list felt that it should be positioned at the start of the questionnaire where it would be visible and more people would know that it was there and that this would be preferable to having a separate sheet. One group disagreed and felt that it would be better as a separate sheet so that they could have it in front of them at all times and that it would save having to flick back and forth. However, both groups agreed that the definitions list needed better signposting. One participant suggested putting a reminder at the top of each questionnaire page to check the definitions page, whereas another felt that when a word is encountered for the first time that is in the definitions page then there should be a comment to say 'go to page 15 or whatever for a definition'.

Each focus group spent time reading over the definitions contained in the list, the outcome of which was that they were pitched at the correct level. Comments were made such as 'they are not big massive words; most people our age would understand most of them'.

They also liked how short the definitions were. The only definition with which participants had an issue was that of a legal high. It was felt that after reading the definition (which is a standard governmental definition) that 'maybe some people might not understand what a legal high is'.

The participants were asked what their understanding was of the following specific terms (which are not included in the definition list): unprotected sex, penetrative sex, sex urges, sexual favour and unwanted sexual advance. They were able to describe unprotected sex as 'sex without condoms' and as sex with 'no protection'.

The term penetrative sex had responses such as 'don't really know', and, although participants understood the term when it was explained, it appears that it is not one they are used to hearing or thinking of. They were able to describe sex urges as 'wanting to have sex; your desires – sexual', but one group wanted this to be included in the definition list. No one was able to offer a definition of the term sexual favour. Unwanted sexual advance was explained as:

if someone tries something on but you didn't want to; not wanting to have sex with someone even though they are trying to.

To revise the terminology used in the questionnaire, the focus groups highlighted that we need to increase signposting to the definitions, to add a few definitions to the list (such as sexual favour and sex urges) and to work on making a couple of the definitions clearer (such as legal highs).

Individual questions

For this section of the focus groups, the research team had highlighted 10 individual questions that they wanted to discuss, the focus group comments for each will be summarised below.

What is your postcode? This question was rather controversial, and, although all the participants stated that they did complete this question, they were not happy at being asked to do it. They felt that it was 'a bit suspicious so you would feel more comfortable if you knew why' and that we should 'write why you need this'.

What do you think you will be doing when you leave school? There was a lot of difficulty expressed with this question. Although participants felt that it was 'good to have options' listed, the suggested options seemed confusing. First, they felt that an option for 'have not decided yet' was missing from the list, as 'you don't know what you are going to do yet so it is hard to just pick one answer'.

Several thought that the option for attending university part time was confusing as they did not think it was possible to do this. They did not have a clear understanding about what was meant by a training scheme. One asked 'where would you put training to be a hairdresser?'

It was suggested that, although examples might be helpful, participants would have preferred fewer options such as attending college, attending university, working, unemployed and do not know.

How well off do you think your family is financially? Many of the focus group participants mentioned that this question caused them difficulty when completing the questionnaire:

I didn't know how to fill this in.

It was clear that 'well off' was not a term that they were used to. One asked 'is the question trying to ask you if your family has money?' and someone else offered the explanation that the question was asking if 'you have what you need and then you have more as well'.

The explanation that was added to the subsequent data collection was welcome but some participants still felt that we could explain this better, as the 'new version still has well off in it so it could still be a bit tricky'.

They felt that people their age would probably find it hard to compare where they are at between the options given.

What is your mother's/father's highest level of education? The focus group participants did not like this question and the majority stated that they were guessing the answer rather than ticking the 'don't know' box. They felt that more examples of the options could be given. This was because they had difficulties understanding what certificates and diplomas were and whether or not a university degree was higher than each of these. They did all understand what an apprenticeship was.

Thinking about future sexual encounters, how likely is it that you . . .? (the Intentions scale) There was a mixed reaction to the response categories in this Likert-scale questionnaire (*Table 16*).

Have you ever drunk alcohol? In the original questionnaire (applied in the pilot study), the question, 'Have you ever drunk alcohol?' was included. During data collection and analysis it was changed to 'Have you ever taken an alcoholic drink (not just a taste or a sip)?' to avoid confusion with drinking and being

TABLE 16 Response categories used and the focus groups' suggested alternatives

Questionnaire	Focus Group 1's suggestion	Focus group 2's suggestion
Extremely likely	Certain	Definitely
	Definite	
Somewhat likely	Possible	Probably
Not sure	–	–
Somewhat unlikely	Not likely	Probably not
Extremely unlikely	Never	Never
	No way	

drunk. Both focus groups agreed that they preferred the new question wording and that it was best to avoid the word 'drunk'.

Whose responsibility is it to avoid an unintended pregnancy (visual analogue scale)? It was felt that this question was clear, as it aimed to see who would be more responsible. Participants thought that the example sheet was very helpful and that integrating it into the questionnaire rather than using a separate sheet should be considered. One suggestion was that it would be nice to include a 'don't know' box.

How comfortable/uncomfortable are you in doing . . . (Comfort Communicating scale)? These questions contain questions for both boys and girls and then also separate questions for boys and girls. The groups agreed that it would be more helpful to 'write the questions so anyone can fill them out' by writing 'boyfriend/girlfriend; partner' instead of the current gender-specific options. Regarding the four-point Likert scale used they had difficulties between a little uncomfortable and somewhat uncomfortable because they look the same. They suggested changing 'a little uncomfortable' to 'Quite uncomfortable', 'Somewhat uncomfortable' to 'Very uncomfortable' and 'Very uncomfortable' to 'Extremely uncomfortable'.

Indicate whether or not you feel like you could do each activity and your degree of confidence (Sexual Self-Efficacy scale) This question was deemed to be very confusing. One person realised that they had completed the question wrong, stating 'I think I ticked this side when I ticked no as well'.

Several people thought that it overused the word 'certain'. They did not like the 'neither certain nor uncertain' option and would prefer 'don't know' instead. Someone pointed out that they expected 'very certain' to be the first option (currently the first option is 'very uncertain') as other questions started on very certain. One person was confused about the need for the uncertain options, as 'if you tick yes why would you need uncertain?'

They wanted the instructions left at the beginning of the question even though no one admitted to reading them while they completed it. The idea of potentially changing the layout to have the 'If yes' questions underneath the 'Could you do it?' questions was welcomed as participants thought that this looked clearer.

Have you had any of the following STIs? This question, in its current format, contains a list of STIs and asks the respondent to tick what they have or have not been diagnosed with. Both focus groups preferred the new question format idea of just asking if you have had an STI and asking the respondent to write in what that was. They thought that people who ticked all the boxes were 'just having a laugh' or might have been 'probably like thinking the question was asking them what they had heard of'.

Other issues

The final section of the focus group discussions gave the participants the opportunity to bring up any other issues that they may have had with the questionnaire. Some issues that arose were the different order of the Likert scales:

question 22 goes from strongly disagree to strongly agree but question 23 goes from strongly agree to strongly disagree.

They also preferred the agree/disagree Likert scales rather than uncertain/certain ones as they have fewer words and are more black and white:

dead on straight agree/disagree are better.

It was also noted that it was good the way you could just skip questions that did not apply rather than having to tick no. One group discussed the fact that there were not really any questions about the wider issues of dealing with UTP (e.g. did you know anyone this happened to? How would you feel if it happened to you? What would you do?). They felt that it 'doesn't really get to the point – it like kinda goes around it'.

Conclusions

In conclusion, these focus groups brought to light a number of interesting problems with the survey instrument, as well as some suggested changes that the research team could make to allow greater understanding for the target age group (Table 17).

TABLE 17 Suggested changes to the questionnaire that emerged from the focus group activity

Section	Suggested change
Questionnaire instructions	Make instructions more visible
	Better integrate definition list
Questionnaire design	Space out the questionnaire
	Randomise questions order
Terminology used	Increase signposting to the definitions
	Add definitions to the list (sexual favour and sex urges)
	Make a couple of the definitions clearer (legal highs)
Individual questions	State why we are asking for participants' postcodes
	Change options for the leave school question
	Consider removing the perceived wealth/'well-off' question
	Change wording of Likert responses in the Intentions scale
	Include a do not know box in the visual analogue scale
	Change layout of the Comfort Communicating scale
	Change wording of Likert responses in the Comfort Communicating scale
Other issues	Change layout of the Sexual Self-Efficacy scale
	Change the format of the STI question
	Ensure standardisation of Likert-scale options throughout
	Consider adding more questions regarding UTP

Mode of administration: electronic versus paper based

Consenting pupils were tested using either a paper questionnaire or an online survey under exam conditions. When making arrangements to facilitate the testing, schools were given the option of how they would prefer to administer the questionnaire. Three schools agreed that they would prefer to use the online survey. Although using an electronic version of the questionnaire had numerous benefits (informed by use of the electronic SurveyMonkey™ online platform in the pilot study), including increased data completeness and the hover-over definitions, its use was discontinued after the first follow-up owing to technical difficulties. Only some pupils from two comparison schools were able to use this mode. During the baseline data collection there were numerous administrative difficulties in using the electronic questionnaire. All three schools had issues, including not being able to log-in and having timing out issues, and a significant number of participants in these classes had to transfer to using a paper questionnaire. For the first follow-up only one school of the original three was happy to try the electronic method again. The software developers were present throughout this data collection to troubleshoot problems and again the same issues occurred. After this session the data collected were not available on the server and these data were unfortunately lost. Owing to these issues, the research team was not confident that the electronic system was fit for purpose and its use was discontinued in order to ensure the safety of the collected data and to maintain positive relationships with both schools and participants who were frustrated with the software issues. In total, 2231 paper versions of the questionnaire were completed and 82 questionnaires were completed online (data from 11 of these were lost as a result of a technical error).

The online survey was able to record the length of time taken to complete the survey; this was recorded at 23 minutes and 45 seconds (range 8–43 minutes). Detailed time records were not available for those completing the questionnaire in paper format but the majority of pupils were able to complete the questionnaire within the constraints of one timetabled lesson.

Conclusions

The questionnaire has been significantly tested, revised and strengthened throughout both the pilot and feasibility study. The pilot was conducted using the SurveyMonkey™ platform as the software developers providing the electronic version were not able to provide a working copy in time to facilitate this. As such, the testing was mainly focused on the clarity of meaning and format of the questions posed as well as the definitions used. It also served to provide insight with regard to the ability and acceptability to conduct this research online in a classroom environment. After the pilot questionnaire and focus groups were completed, significant changes were made to the questionnaire both in terms of the definitions given and the wording of some questions. At this stage some questions and a scale were removed owing to limited variability in participant responses. Both paper questionnaires and an online electronic questionnaire were utilised during the feasibility study. Schools had a choice of which administration mode would be used and three schools selected to use the electronic questionnaire. Unfortunately, there were numerous issues at baseline in these three schools, including participants being unable to access the questionnaire online and being timed out. Many participants had to switch to using paper questionnaires. At the first follow-up, only one school agreed to use the online questionnaire as a result of these issues, and the software developers attended that session to troubleshoot problems. Unfortunately, the issues persisted and we were left with no usable data from that data collection session. It was then that the research team decided not to continue with the electronic version owing to its instability and to loss of data. Nevertheless, persevering with the paper questionnaire, minor amendments were made to questions to improve readability, removing questions that did not need to be asked at each time point, and a separate page containing definitions that mirrored those in the electronic version was produced. Based on cognitive interviews after the final data collection wave in the feasibility study, we determined that further changes were required. These included simplifying and standardising the Likert-scale options and increasing the privacy of the participant by ensuring that skipped sections would be replaced with an equivalent number of questions and randomising sections that would be incorporated into the questionnaire for a proposed future trial.

Chapter 5 Recruitment, randomisation, allocation and retention

Introduction

Feasibility trials offer unique opportunities to examine anticipated and unexpected challenges to successful recruitment and retention and to explore possible solutions suited to the particular context in which the trial is taking place. The present study aimed to (1) establish trial recruitment and retention rates to inform a larger effectiveness trial; (2) assess acceptability of participation, including equality of engagement in and across schools of different socioeconomic and religious types and schools allocated to the comparison group; and (3) identify optimal recruitment and retention strategies for a larger effectiveness trial.

We begin with a brief review of the literature on factors thought to influence participation in research and techniques reported to improve recruitment and retention in randomised controlled trials (RCTs) in general, and school-based health research in particular. We detail the anticipated challenges of recruitment and retention, the multilevel strategies used in the current study to recruit and retain schools, teachers, pupils and parents and their yield, as well as the challenges we encountered during the process. We conclude with lessons learned for a future full-scale trial.

Why is successful recruitment and retention important: a background literature review

Randomised controlled trials generally require large numbers of participants and follow-up over long time periods. Recruiting adequate numbers of participants and retaining them in the study for its entire duration, although challenging, is essential for ensuring internal and external validity and reducing bias that is introduced if certain groups of participants refuse participation or withdraw from the study.

However, participation rates in general have been decreasing over the past decades and it is increasingly difficult to recruit and retain participants to RCTs.⁹⁶ Fewer than one-third of publicly funded RCTs reach their recruitment targets within the specified time frame and more than half need to be extended owing to recruitment difficulties.⁹⁷ This can result in extended study duration, increased expenditure and findings that are not statistically accurate, because recruitment may be biased towards particular groups.⁹⁸ In worst case scenarios, insufficient recruitment or retention can result in a trial being stopped or a delay in the roll-out of an intervention with serious public health benefits.⁹⁹

Factors influencing recruitment and retention

It is widely recognised that the proliferation of research studies, marketing surveys and opinion polls over the past decades, and the resulting increase in the number of participation requests received by both individuals and sites, has led to a situation whereby increasing numbers of people refuse all (or all but the most immediately relevant) requests to take part in research.¹⁰⁰ Other factors thought to influence research participation include the characteristics and demographics of potential participants, factors related to the study design, and characteristics of the investigator(s).^{101,102}

Demographic factors that are associated with increased likelihood of participating in research include being younger, female, married, of higher SES, of higher educational attainment and in employment.^{96,101,103} Factors relating to the study design include the length of time participants are expected to engage with the study, the potential burden placed on them, the treatment being offered, concern about allocation to the control group and the focus of the study (in particular whether or not it is sensitive/controversial).^{98,101} The characteristics of the organisation responsible for the research and its representative investigators, particularly perceptions of their credibility, is also thought an important influencing factor.^{98,104}

In reference to school-based research, Pound *et al.*¹⁰⁴ found that perceptions of the social value of the study (i.e. value to students and the community and perceived benefits of taking part) and confidence in the organisation responsible for the research strongly influenced the decisions of school management to take part in a trial. Barriers to recruitment included the amount of effort involved for the school, interest in the project and commitment to other research. In a qualitative investigation of the views of school superintendents and principals, Befort *et al.*¹⁰⁵ found that school management was interested in research projects that (1) provide tangible benefits to their school; (2) are consistent with their academic mission; (3) are not burdensome; (4) do not take place during exam time or other busy periods; and (5) are credible and non-controversial.

Strategies to optimise recruitment and retention

In a recent systematic review of methods to improve recruitment to RCTs, Treweek *et al.*⁹⁸ concluded that effective interventions include telephone reminders to non-respondents; the use of opt-out rather than opt-in procedures; and open designs whereby participants know which treatment they are receiving in the trial. Over the years, others have reported that recruitment facilitators include engagement with the target population when developing the intervention and preparing participant information about the study;¹⁰⁶ a personalised and culturally sensitive approach to participants;^{99,107} designing recruitment processes that are aimed towards clearly highlighting to potential participants the beneficial outcomes of taking part and addressing any barriers or perceived negative outcomes;¹⁰⁸ providing research and implementation support by providing a dedicated research team contact;¹⁰⁹ minimising the workload for participants by adapting trial processes so they are in line with usual ways of working at the site;¹⁰⁹ providing financial or other incentives;²⁹ and good communication and expressions of appreciation to site facilitators and participants.^{108,109} Although some have suggested the value of using technology such as internet-based questionnaires¹¹⁰ and the use of video to provide trial information^{111–113} to improve recruitment, a recent systematic review⁹⁸ concluded that their effect is not clear. At the very least, however, the use of video does have obvious benefits in terms of recruiting participants with low literacy levels.¹¹⁴

A number of studies have reported recruitment and retention facilitators that are specific to schools. Lytle *et al.*¹⁰⁸ argue that an essential strategy is to adjust the recruitment process to suit the culture of each school and to plan to impact on a number of individual-, environmental- and behavioural-level factors. In addressing individual factors, they sought to help the school decision-makers recognise the importance of the research projects goals and objectives. They did this by emphasising the proximal and distal public health benefits of the programme intervention and highlighting the value and credibility of the programme using expert testimonials. In addition, they increased the primary decision-makers' self-efficacy in being able to 'sell' the programme to implementers by offering to speak to implementers themselves. The researchers sought to influence environmental factors by 'reducing external barriers to acceptance, enhancing social norms, and by committing future support to schools through training and materials provision'.¹⁰⁸ To achieve this they shared testimonials from participants who took part in the pilot trial, adjusting recruitment procedures to suit individual schools, providing a clear outline of roles and responsibilities of both school and research team members, facilitating discussion on the benefits and perceived barriers to taking part and providing external support (e.g. training, paying for substitute teachers), which would enhance implementation in intervention schools. Targeting behavioural factors, the team provided incentives in the form of training, research and intervention materials and support during implementation. For schools randomised to the control group, materials were provided at the end of the trial. In addition, providing refreshments at any meetings was seen to increase attendance as was sending personal thank you notes to all involved from the research team following such meetings. Obtaining 'intention to act' was operationalised in the recruitment process by asking individuals to sign a contract. Although these were not considered legally binding they were part of a behavioural process important for formalising the agreement. Lytle *et al.*¹⁰⁸ also imply that marketing techniques can be of value in recruiting for schools. For example, they sent a letter to schools saying that 'only two more slots' were available and used videos with end-user testimonials to increase credibility and perceived acceptability.

Aarons *et al.*¹⁰⁷ argue that it is essential to consider each participating school's needs in planning intervention and data collection activities. They argue that it is essential to communicate to decision-makers at the recruitment stage that the research will not interrupt the 'ebb and flow' of the school. In particular, time and

timing are important considerations for both recruitment and implementation planning in schools; although study deadlines must be met, this needs to be balanced with the school timetable.¹⁰⁷ Summer, Christmas and Easter closures as well as half-term breaks in autumn and winter must all be considered, along with school-specific staff development closures, public holidays and exam periods. Furthermore, the school curriculum is often overcrowded, with some schools less willing than others to remove pupils from exam subjects. In this regard, Befort *et al.*¹⁰⁵ suggest that, from the outset, researchers should be very clear about time commitments and how the study may be used to improve the school's academic mission.

Financial incentives have been reported to be beneficial for recruiting and retaining both schools and pupils.²⁹ Harrington *et al.*¹¹⁵ suggest that if schools are concerned about possible allocation to the control group (thereby depriving their pupils of a potentially beneficial intervention), a delayed treatment condition rather than no treatment may be an added incentive for schools to participate.

Potential barriers to and facilitators of successful recruitment and retention

Table 18 details potential barriers to and facilitators of successful recruitment and retention.

In conclusion, as outlined in Table 18, it was anticipated that a number of barriers to and facilitators of recruitment could impact on our ability to reach recruitment targets and retain participants in the study. In general, it was anticipated that key influences would be whether or not (1) the school was currently or recently involved in a research project; (2) school management, teachers and parents saw RSE as a priority subject and teenage pregnancy as a current concern; and (3) school management, teachers and parents perceived both the research project and intervention as credible, beneficial, compatible with their needs, ways of working and ethos, and not burdensome in terms of time and resources. Although the initial intervention design and development process sought to overcome potential intervention-level barriers (see Chapter 3), it was also anticipated that important research-level facilitators of recruitment and retention would include (1) approaching schools that were more likely to see RSE as a priority subject and teenage pregnancy as a current concern; (2) encouraging buy-in and intention to act by making roles and responsibilities clear from the outset, assigning a trial champion in each school and building positive relationships with all participants; and (3) providing token incentives, reimbursement of expenses and research support.

TABLE 18 Potential barriers to and facilitators of successful recruitment and retention

Recruitment barriers	Recruitment facilitators	Retention barriers	Retention facilitators
<ul style="list-style-type: none"> School already involved in research RSE not a priority Intervention incompatible with needs Intervention incompatible with ethos Time constraints (overcrowded curriculum) Timing: conflict with exams Teacher discomfort delivering intervention Pupil discomfort at receiving intervention Parents not in favour of RSE provision in school and/or potential distraction from exam subjects 	<ul style="list-style-type: none"> Involvement in research desirable RSE a priority Intervention compatible with needs Intervention compatible with ethos Short, 'off the shelf', credible, non-directive intervention Flexibility in relation to subject in which intervention delivered and by whom Face-to-face teacher training and support from research team Teacher self-efficacy Parental involvement 	<ul style="list-style-type: none"> Time constraints Conflict with exams Teacher discomfort delivering questionnaire Pupil discomfort completing questionnaire Pupil loss of interest completing questionnaire Parents not in favour Staff changes Lack of incentive for comparison schools 	<ul style="list-style-type: none"> Positive relationships with research team Support from research team Buy-in and intention to act Roles and responsibilities transparent Intervention incentive Reimbursement of research expenses Token incentives for pupils, teachers and administrators (chocolate, plants, thank-you cards)

Recruitment targets in the current study

Schools

Initial and revised recruitment targets are described below. In 2013, there were 210 registered post-primary schools in NI. NI has a unique education system and post-primary schools can be broadly categorised as 'secondary' ($n = 133$) or 'grammar' ($n = 68$), with the latter using academic ability to select pupils. Various management structures also exist, with 'controlled' schools ($n = 75$) managed by one of the five NI Education and Library Boards and 'voluntary' and 'maintained' schools ($n = 135$) managed by a board of trustees. The Roman Catholic (RC) Church manages a significant number of voluntary (RC maintained) secondary ($n = 68$) and grammar ($n = 29$) schools. Although religion is not a criterion for attendance at NI schools, most pupils at controlled schools are from Protestant denominations and most of those attending RC maintained schools are Catholic. There are also a number of 'integrated' schools ($n = 20$), which aim to provide a religiously and culturally mixed environment.

Eight post-primary schools (five controlled secondary schools and three RC maintained secondary schools) in NI were excluded from target recruitment because they had < 30 Year 11 pupils and one was excluded because it was an Irish language school (secondary other maintained). The remainder of registered post-primary schools were included as targets for recruitment (*Box 1*).

In order to capture this diversity, and reflecting the aim to examine the acceptability of the intervention in different school types, the following seven schools were initially sought for recruitment: one integrated; one controlled grammar; one voluntary 'other managed' grammar; two voluntary RC grammars; and two schools of any type in deprived areas. Our preliminary research indicated potential challenges in recruiting RC schools owing to the fact that some may perceive an 'abstinence-plus' intervention such as *If I Were Jack* to be incompatible with the Catholic ethos. Conversely, it was anticipated that there may be greater uptake of the intervention in deprived areas where teenage birth rates are higher. For this reason two RC grammar schools and two schools in deprived areas were targeted for recruitment and one of each was randomly assigned to the comparison and intervention groups.

BOX 1 Registered post-primary schools in NI

Registered post-primary schools for target recruitment

Secondary (133)

Controlled (48).

Controlled integrated (5).

Grant maintained integrated (15).

RC maintained (65).

Grammar (68)

Controlled (17).

Voluntary: RC managed (29).

Voluntary: other managed (22).

Teachers and other school staff

One teacher who would act as main trial contact within each participating school was targeted for recruitment. This individual would be asked to work with the trial manager to co-ordinate baseline and follow-up data collection with pupils, to recruit teachers to deliver the intervention (if necessary) and to participate in an interview regarding their perceptions of taking part in the research and (if appropriate) current RSE provision in the school. In intervention schools, at least one teacher was targeted for recruitment to deliver the intervention to Year 11 pupils and to take part in an interview about their experiences of using the intervention. In addition, within each school at least one school administrator/secretary to support the research team and make contact with parents was targeted for recruitment. Although not an initial consideration, the need arose to recruit a school Information Technology (IT) technician who could support use of the interactive film in intervention schools and use of the online survey in all schools opting to use this method of data collection.

Pupils

The target population was all Year 11 pupils aged between 14 and 16 years in participating schools. Pupils were excluded if their parents/guardians withdrew them from the study, if they declined to take part or if they were unable to read the questionnaire owing to language difficulties (i.e. if English was not their first language). Pupils with reading difficulties and/or learning disabilities were included if they wanted to take part and if teachers thought that they would be able to understand and complete the questionnaire (with or without the aid of a teaching assistant or researcher reading the questionnaire aloud and explaining problematic words). Based on the average size of Year 11 in schools in 2011/12 (mean = 114; median = 113) and allowing for an 80% consent rate, it was estimated that approximately 730 pupils would be recruited to the study.

Parents

At least one parent or guardian of each participating Year 11 pupil in the intervention group was sought for recruitment to attend a 1-hour parents' and guardians' information and discussion session at their child's school. Based on anecdotal evidence from teachers regarding difficulties engaging parents in non-academic activities, it was estimated that parent/guardian representatives of approximately 50% of Year 11 pupils would attend these sessions, which would result in around 200 participating parents.

Recruitment strategies

Recruitment took place over a 4-month period (May–June and September–October 2014), which allowed for no possibility of contact with potential participants during the summer break period (July and August). Schools were retained in the study for a period of 12 months from baseline data collection.

Although an aim of the study was to assess the relative importance of anticipated barriers to and facilitators of recruitment and retention, as well as other potential influencing factors, it was intended that the recruitment and retention strategies for the feasibility study would mimic best practice so that their value and feasibility in a full trial may be determined. The strategies employed to achieve this are described below.

Recruiting schools

Three strategies were used to recruit targeted schools: (1) RSE teacher training events; (2) personal introductions by members of advisory and steering groups; and (3) 'cold-call' invitation. Regardless of the strategy used, all principals [and, when applicable, the RSE co-ordinator or PC vice principal (VP)] were posted a formal letter of invitation and information sheet, which included detailed information on what would be involved on consenting to participate, including the estimates of required time and resources (see *Appendices 2 and 3*). This was followed, within 1 week of posting the letter, with a telephone call to the principal. In most instances, several more attempts to make contact with the principal and/or other contact (if suggested by the principal at first contact) were required before a decision on whether or not they would like to participate was made. In most cases the decision was made following a meeting with

the principal or PC VP and, for the majority of schools, a teacher [such as the designated RSE co-ordinator, Head of Year 11, Head of LLW curriculum/personal development (PD), or Head of Religious Education (RE)]. During this meeting the research fellow described the intervention and the research study and explained what would be expected of the school, teachers, pupils and parents, should they agree to participate. In order to promote the credibility of the research project potential participants were told that the study was funded by the NIHR and the PHA NI and had received ethics approval from QUB. In order to promote the credibility of the intervention and impact perceptions of its potential benefits, the meeting also included the presentation of a 5-minute video of health and education experts talking about the resource and its potential benefits for use in the classroom and testimonials from teachers who had used the intervention during the pre-piloting development phase.

Strategy 1: recruitment at Relationship and Sexuality Education training events

This method was chosen as the primary recruitment strategy with the intention that it would optimise the potential to recruit schools that saw RSE as a priority subject and/or had an interest in developing their RSE curriculum. In addition, it was thought that the opportunity to promote the intervention and research process among key school stakeholders at a statutory funded training event and to address any concerns in situ would lead to positive perceptions of the credibility of the research team and benefits of involvement in the trial.

These day-long events, which take place approximately seven times annually, are funded by the PHA NI and facilitated by two Sexual Health Coordinators from the BHSCT's Sexual Health Training Team. Although the content of the training varies, the sessions generally include subjects such as healthy relationships, STIs, contraception, childhood trauma, emotional intelligence, sexual orientation and RSE policy development. On average, representatives (usually the PC VP or RSE/LLW co-ordinator) from nine schools across NI attend each event following direct invitation from the facilitators. Attendance at the event is followed with a voluntary all-staff half-day RSE training session in each school. Over the 10 years that the events have been running, there has been total post-primary school attendance of between 40% and 100% across the five NI Education and Library Board areas. Schools that do attend report expectations that they will improve their provision of a statutory part of the curriculum. Those who do not attend report time pressures as the primary influencing factor.

On request to the facilitators we were invited to attend two of these events in April and October 2014 and to give a 30-minute recruitment presentation. A member of the research team introduced the intervention and provided an overview of the research. It included presentation of a 5-minute video of health and education experts talking about the resource and its potential benefits for use in the classroom and testimonials from teachers who had used the intervention during the pre-piloting development phase. Teachers in attendance were asked to provide their contact details if they were interested in receiving more information about the research.

Following the events schools were categorised according to school management type and deprivation proxy (indicated for the purposes of the current study by percentage of pupils at the school eligible for free school meals). The schools approached following these events were therefore selected on the basis of (1) their expressed interest and (2) their fit with recruitment criteria. Schools attending the event and meeting these criteria that declined to participate after initial contact were replaced by the next school from the list of all eligible schools attending the event.

Strategy 2: recruitment following introduction by steering and advisory group members

This strategy was used to contact five schools and as an aid to recruit the target of two RC grammar schools and one voluntary other managed grammar school, all of which were difficult to recruit, with low attendance of representatives at the RSE training events. An additional RC maintained secondary school was recruited this way when the recruitment target was adjusted. Only one RC grammar representative attended the RSE training events and, although three voluntary other managed representatives attended,

all declined to take part. It was anticipated that this strategy would help to increase the perceived credibility of the trial and the possibility of arranging an initial meeting with school management.

In implementing this strategy, steering and advisory group members were asked if they had contacts in post-primary schools and if they would be willing to (1) suggest schools that might be amenable to receiving information about the research and/or (2) contact a representative of the school introducing the trial manager and seeking an expression of interest in receiving a letter of invitation from the research team. One steering group member directly contacted two voluntary other managed principals (by telephone) on behalf of the research team asking if they would be open to contact from the research team, and two other steering group members recommended (but did not introduce) two RC grammar schools that they thought might be amenable to participate. One advisory group member introduced the research team (via e-mail) to representatives in two RC grammar schools and one RC maintained school.

Strategy 3: recruitment through cold-call invitation

This strategy was used to contact five RC grammar schools and one voluntary other managed school that met the recruitment criteria but with which no contact had been established prior to sending the letter of invitation. Two of the RC grammar schools were recommended by steering group members. In addition to including the standard information sheet (which contained minimal information on the intervention), steering group members' advised the inclusion of a flyer with promotional detail on the *If I Were Jack* intervention, testimonials from experts and end users and a link to the project website as well as a letter of invitation, which stated that there was 'one place remaining' for a RC grammar/voluntary other managed school.

Recruiting teachers and other school staff

The initial meeting between the trial manager and the school generally included either the principal or PC VP and a teacher who had attended the RSE training event or had responsibility for RSE/LLW. The main school contact following school consent to participate (the trial champion) was either the head of LLW and RSE co-ordinator (five schools); head of RE (one school); head of Year 11 (one school); or a senior teacher (one school).

Participating teachers who would deliver the intervention if randomised to the intervention group and/or facilitate delivery of the questionnaire at baseline and follow-up were identified by the principal/PC VP or trial champion prior to baseline data collection and randomisation. These teachers were then invited to attend a 30-minute meeting with the trial manager at the outset of the study. During this meeting they were provided with information sheets and the research was explained to them with the aid of Microsoft PowerPoint version 14 (Microsoft Corporation, Redmond, WA, USA) slides and a study flow chart. They were offered an opportunity to ask questions and consent to taking part in the research. In only two schools did the RSE co-ordinator attend this meeting, both of whom indicated that they had not yet identified other teachers to take part in the research. Both of these schools assigned teachers to facilitate the questionnaire data collection without any input from the researcher. One of these schools was later assigned to the intervention group, at which point an additional teacher was provided with an overview of the research during the teacher training session. In one school all members of the teaching staff were provided with an overview of the research during a staff training day. During the information sessions teachers were asked to consent to take part in an interview or focus group discussion and these were arranged with individual teachers or via the trial champion at the appropriate time. At the end of the study the trial champions in all schools were presented with a box of chocolates or bunch of flowers and an individualised thank you card from the research team.

At the initial meeting with school management the trial manager asked if she could be introduced to a school administrator who might help with administrative aspects of participation (i.e. provision of class lists, contact with parents, expenses). In five schools the trial manager was introduced to this person and in three schools contact only ever took place via e-mail or telephone. Following initial labelling and posting of information sheets and consent forms to parents, these individuals were presented with a small plant and note of thanks from the research team.

Although not initially anticipated, in some schools the trial manager had contact with the school's IT technician. In intervention schools this involved liaison with the technician to ensure that pupils could access the *If I Were Jack* film and online resources and, in schools that opted to allow pupils to complete the questionnaire online, the IT technician was asked to test access to the survey and help with troubleshooting problems with this (see *Chapter 7*).

Recruiting pupils

After the school and teachers had consented to take part, parents/guardians of all Year 11 pupils were posted information sheets and given 2 weeks to withdraw their child from the study before the research was brought to the attention of pupils. During the teacher's information session, the trial manager offered to spend a class period with pupils prior to data collection, during which the research would be explained in detail to them. All schools declined this offer stating that, owing to time constraints, it would be preferable to provide this information at the beginning of the baseline data collection session. Teachers were therefore provided with information sheets to distribute 1 week prior to baseline data collection to Year 11 pupils whose parents had not withdrawn them from the study. They were asked to encourage pupils to read the information sheet and inform them that they would have an opportunity to ask questions about it and decide whether or not they wanted to take part before completing the questionnaire the following week.

At the beginning of the baseline data collection sessions, either the trial manager or a trained research assistant spent 15 minutes explaining the research to pupils, giving them an opportunity to ask questions and asking them to complete a consent form indicating whether or not they wanted to take part. As a means of saying thank you to pupils for taking part in the study (and an incentive suggested by teachers), chocolates and sweets were provided to students after they had completed each questionnaire. Pupils who declined to participate or whose parents opted them out were supervised by a teacher in a separate classroom or the school library during data collection.

Participating teachers were asked to recruit volunteers from their class groups (six pupils minimum) to take part in a focus group discussion with a researcher (immediately following implementation in intervention schools and immediately following the 9-month follow-up in comparison schools). Pupils were provided with drinks and snacks during these sessions as an incentive for participating.

Recruiting parents

Parents or guardians of participating Year 11 pupils in the intervention group were invited via letter to participate in a 1-hour parents' and guardians' information and discussion session at their child's school. At the request of the research team (and owing to a very small number of reply slips indicating attendance or non-attendance) a reminder text message was sent from the school to parents the day before the session. In three schools this session was managed and facilitated by a teacher and in one school (owing to teacher sick leave) by the PI. Schools were encouraged to run the event in the evening to facilitate attendance by working parents.

In an attempt to reach parents who did not attend the session, a 6-minute video for parents/guardians containing key messages was posted on YouTube. School administrators texted a link to the video to parents.

Parents who attended the parents' session were invited to participate in a focus group discussion with a researcher immediately following the session if that suited them or to provide their contact details if they wished to take part at another time. In addition, the YouTube video provided contact details for any parents wishing to take part in a focus group.

Following implementation, parents of participating pupils were sent a text message containing a link to a short survey which asked parents for their views on the intervention.

Methods: how we evidenced our data on recruitment

Data collection consisted of three elements

1. Number of expressions of interest at RSE training days, invitation letters sent, responses received, telephone calls made, e-mails sent, participants declining participation and participants agreeing to take part in the study were all recorded in a database to allow the calculation of recruitment and retention rates and calculation of time taken for participants.
2. Time spent by the research team on recruitment activities, including delivery of recruitment presentations, preparation and posting of invitation letters, making follow-up telephone calls and sending e-mails to obtain expressions of interest, and arranging and conducting introductory meetings were recorded in researcher activity logs and used to estimate total time spent on recruitment activity.
3. Qualitative data were obtained from a combination of field notes, records of e-mail communication and contact notes following telephone conversations with participants who declined to participate, documented meetings with steering group members, and semistructured interviews with principals, VPs, teachers and parents recruited to the study.

Data analysis

To calculate recruitment and/or retention rates, a percentage was derived from the total number of invitations sent by school management type and the resulting number of schools, pupils and parents recruited.

To calculate the time associated with the various recruitment strategies and overall time spent on recruitment and retention activities, estimated time spent was totalled and divided by the number of schools, pupils and parents successfully recruited. This resulted in the total amount of time spent by the research team per school randomised.

Qualitative data were organised using NVivo 10 (QSR International, Warrington, UK) and analysed using a form of thematic analysis based on the six steps proposed by Braun and Clarke.¹¹⁶ This involved moving between inductively derived codes emerging from the data and searching for data on pre-defined themes outlined in our topic guides. These inductively and deductively derived codes were analysed to form overarching themes.

Results

The Consolidated Standards of Reporting Trials (CONSORT) flow diagram is depicted in *Figure 4*.

Randomisation and allocation

Schools were the unit of randomisation, with four randomly allocated to the intervention group and four to the control group. After baseline data collection, schools were randomised as pairs to ensure that one of each type was in the intervention arm. The schools were grouped into four pairs based on their school management type: secondary schools in deprived areas, Catholic schools, grammar schools and other types. This process was conducted by the Northern Ireland Clinical Trials Unit (NICTU), a UK Clinical Research Collaboration-registered clinical trials unit, overseen by the trial statistician, using a method of simple randomisation completed using NQuery version 3.0 software (Statsols, Cork, Ireland).

Recruitment of schools

In October 2014, following unsuccessful attempts to recruit a second RC grammar school, recruitment targets were revised to maintain the diversity of schools included in the study but to broaden the scope to include RC secondary schools that, despite being RC schools, are not as academically driven as RC grammar schools. The revised target was eight schools of the following types: two secondary schools of any management type in deprived areas, two controlled secondary schools, two RC maintained schools and two grammar schools.

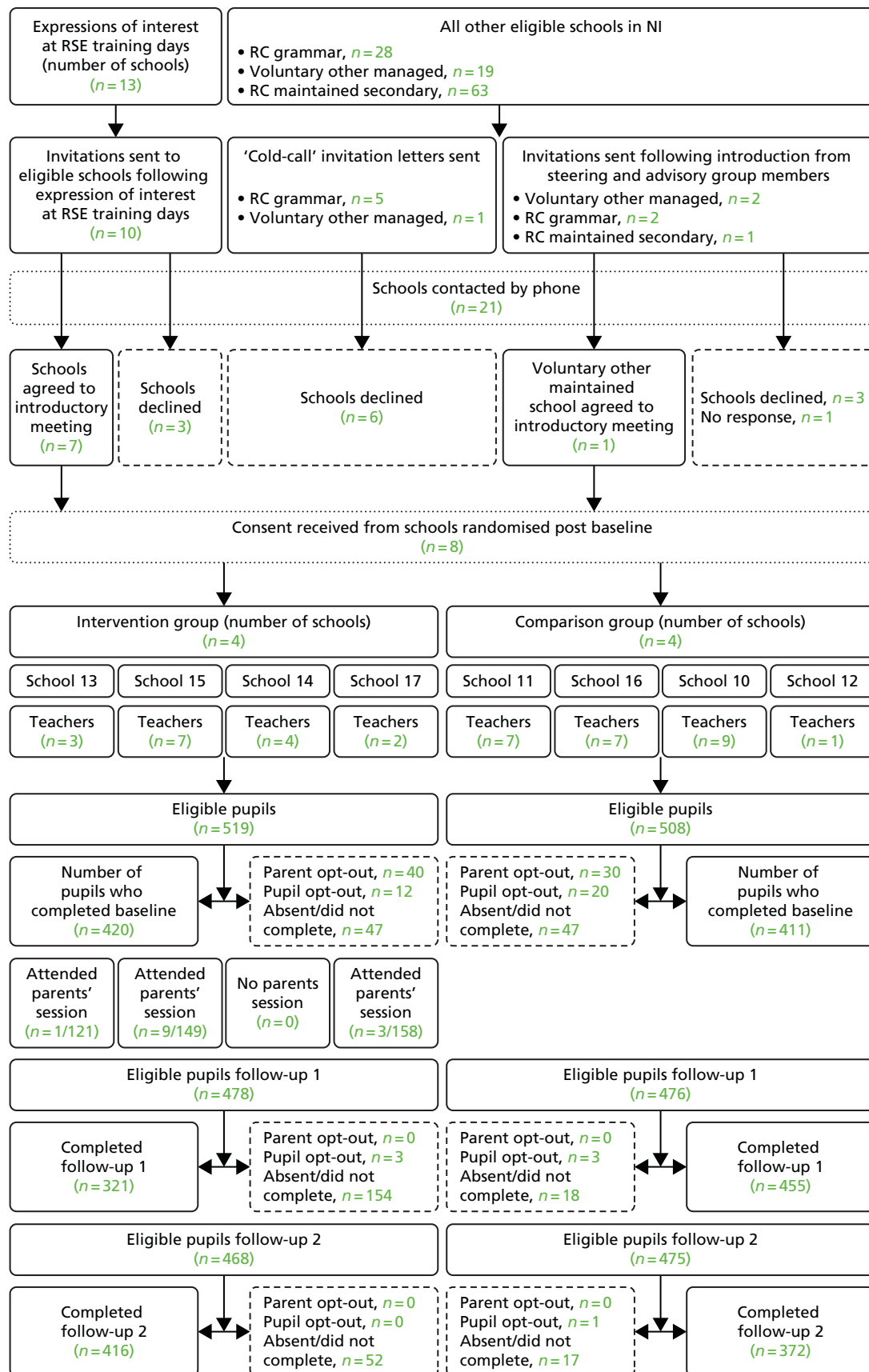


FIGURE 4 Consolidated Standards of Reporting Trials flow diagram.

A total of eight schools were recruited (see *Figure 4*). The over-recruitment of one additional school was the result of the yield from the final attempt to recruit RC schools of any type following difficulties recruiting RC grammar schools.

Invitations were sent to a number of RC maintained schools and two responded on the same day with a decision to take part. It seemed unwise, and possibly unethical, to contact schools about a study and not invite them to participate once they had expressed an interest in doing so. Recruitment of schools via RSE training events was by far the most successful strategy, leading to 70% of schools invited by this method ($n = 7$) being randomised into the study. Invitation following introduction by a steering or advisory group member led to the recruitment of one additional school (a 20% recruitment rate). Cold-call invitation was unsuccessful, with all six schools approached declining to take part.

Targets for recruiting schools of different socioeconomic and religious types were met, but required more intensive work to reach particular school types and adjustments to initial recruitment specifications in order to achieve the recruitment target within the specified timeframe. As illustrated in *Table 19*, our main challenge was in recruiting RC grammar schools (i.e. RC schools that use academic ability to select pupils) and voluntary other managed grammar schools (i.e. non-RC Church or privately funded schools that use academic ability to select pupils). Although the overall school recruitment rate was 38% (100% for integrated, controlled grammar and controlled secondary schools), the recruitment rate for RC maintained secondary, RC grammar and voluntary other managed grammars was 67%, 13% and 17%, respectively.

Between June and October 2014 one of eight RC grammar schools approached and one of six voluntary other managed schools approached was recruited. Faced with a recruitment deadline of the end of October it was decided to revise initial recruitment targets to recruit RC schools of any type rather than just RC grammars. One RC grammar and one RC maintained secondary in a deprived area had already been recruited, and so it was decided to recruit one additional RC school of any type in a non-deprived area, which could be paired with the RC grammar for randomisation. This was achieved by inviting schools from the list of those attending the RSE training events.

As outlined in *Table 20*, a total of 13 schools approached declined to participate in the study. All but one of these schools made this decision prior to meeting with the trial manager. The most common reason for non-participation ($n = 4$) was that having considered the information sheets, school management and/or the teacher responsible for delivering LLW considered that there was no time available within the current curriculum at Year 11 to deliver the intervention and take part in the research. Three schools also reported that they were already involved in another research project and could not accommodate a further study at that time. Two other schools indicated that owing to staff changes (maternity leave and a change in the LLW team) they did not think it was an appropriate time to take part. Two schools declined to take part without providing a reason. The PC VP and Head of RE of one RC grammar school met with the trial

TABLE 19 School recruitment (June–October 2014)

School recruitment	Integrated	Controlled secondary	RC maintained secondary	Controlled grammar	Voluntary RC grammar	Voluntary other managed grammar	All
Number of schools contacted	2	1	3	1	8	6	21
Number of schools recruited	2	1	2	1	1	1	8
School recruitment rate (%)	100	100	67	100	13	17	38

TABLE 20 Reasons for non-participation by school type and deprivation

Reasons for non-participation	Number of RC maintained secondary	Number voluntary RC grammar	Number voluntary other managed grammar	All school types
No space in LLW curriculum	1	2	1	4
Currently involved in other research		2	1	3
Not a suitable time owing to staff changes		1	1	2
Declined without providing reason		2		2
Intervention incompatible with ethos		1		1
Intervention incompatible with needs			1	1
All non-participants	1	8	4	13

manager prior to making their decision as they were concerned that the intervention might not be compatible with their school ethos. Having expressed positive views that they felt it was in line with their ethos at the meeting, they later declined to take part having consulted with the school Chaplain who felt that the intervention was not in fact compatible with the school ethos. Although a number of schools mentioned at first contact that they did not have any issues with teenage pregnancy in their school, only one cited this as their primary reason for non-participation.

The schools that did participate in the research reported doing so for a number of reasons, primary among which was their desire to improve RSE provision for their pupils and their belief that the *If I Were Jack* resource would be of benefit to their pupils. Schools in deprived areas were particularly interested in taking part because of their current and past experiences of teenage pregnancy in the community.

Principals indicated that they were approached several times a week to take part in research, and, although all appreciated the potential benefits of research they were often too busy to respond to such requests. All agreed that direct face-to-face contact with them or a subject teacher was the optimal strategy:

If [an invitation] just comes as an e-mail there is a fair chance it'll end up in the bin [...] If it's preceded by a phone call there is probably a better chance [it'll be considered].

If you just send something in and it comes to me, it could go over my head. If you send it to my teacher or you engage somebody or you phone the school up and say 'Could I come in to chat to the Principal?' or 'Could I come in to speak to somebody?' rather than sending a letter, I think that's the way to hook people in . . . Personal contact is key.

One principal summed up how she went about considering research participation:

We would regularly get asked for research, maybe three or four times a week, so the volume of research out there, I think, is immense, and the time restraints that that places, depending on the type of research and what the investigator is looking for, specifically, can impact whole school activity, so we need to be very careful in terms of what we select and the benefits that are going to be achieved to the students. But then, also, I do think we've a wider responsibility as educators to look outside the students sometimes and possibly to learn from the practice of research and contribute to it on a more holistic educational basis. So, it's, for me, it's trying to balance up the benefits of that.

Principals agreed that a number of considerations were important in helping them to make a decision about whether or not to take part. Central among these were the potential burden on pupils, especially those in exam classes, the burden on teachers and the credibility of the project:

Firstly, if there's any credibility in what's being done. Secondly, if it can be fitted in with minimum disruption. If it's going to affect exam classes there's almost no chance.

Principals were asked what kind of things do they consider before deciding whether or not to take part.

Well, the first thing I would look at is, is it in an area of interest that we can contribute to that is very specific to my school? Is it an area that the students can benefit from? So, with the Jack project, I felt it was a wee bit innovative and that there were potential useful resources from it. The [other] things that I look at are what are the time constraints and the commitment for the students and the staff?

Several principals noted that 'Area Learning Communities' or other head teacher forums such as the 'Catholic Heads Association', which were attended regularly by principals, might be possible venues for presenting research and recruiting schools. Others noted that buy-in from teachers was a must and that often a good way of reaching the principal is through a subject teacher.

So, sometimes, if a specific teacher in an area is going to drive it and sees it as very beneficial, is going to inform practice and that, they would come to me and they would sell the research if they are going to lead it. The difficulty for me is sometimes, if there's not an original buy-in from staff, it can prove very difficult to manage . . . so if you get the hook through somebody else, if it's a subject-specific area, that could be a driver for running it as well.

Sometimes I get e-mails from folks I've never met or have no connection with, so they haven't really much hope of being successful. Mmm, it depends on how the approach is made and on the reason behind it [the research].

I suppose for me the best time to get me is either early in the morning, between eight and quarter to nine or later in the afternoon, sort of, between half past four and six. That would be times when I'm not out and about or engaging with kids or staff.

Principals especially did not want pupils in significant exam years to be disrupted with external research studies.

If you're wanting to do it with Year 11 to 14, especially Year 11 and 12, there's hardly a week goes by where they're not involved in some kind of controlled assessment . . . I won't take kids out of English and Maths or maybe even other GCSE subjects to do [research].

Principals also had an especially strong message for researchers in terms of taking some of the responsibility for the organisation of the research within the school, especially in terms of conducting the data collection.

[I would immediately decline to take part in research projects] that are going to be very time-consuming . . . or, where projects put the onus on the school – 'Could you get us a group? Here's the list – could you go away and do it, and when you're finished, could you bring it back to us and I'll pick it up from you?' and you're like 'What?!'

Principals were asked how important monetary incentives, such as getting the *If I Were Jack* resource to use at the end might be in a future trial. They agreed that monetary incentives would be an important facilitator of participation:

Very important. They would be the enticement to get you involved. It sounds very mercenary and I don't mean to be mercenary in this day and age, but if I'm going to . . . if it's going to be time and

energy with students and staff and commitment, and if the benefits are not solely related to students and staff and outcomes, then there's got to be a reason why you would do it.

One principal in the control group suggested that having access to the resource was a more important incentive than money to them:

We now have access to the Jack resources. From our point of view that is probably more valuable . . . that's probably a better incentive than money.

Reasons principals chose to participate are detailed in *Table 21*.

Schools took between 1 and 19 days (mean = 6 days) to confirm their decision. Two schools did not respond with a decision despite several attempts at contact. Allowing 1 week following postage of the introductory letter, this means that it took an average of 2 weeks to receive a participation decision from schools.

For an overview of the number of contacts made, outcome and time taken to decide by schools approached see *Appendix 8*.

Recruitment of teachers

A total of 40 teachers were recruited across the eight participating schools (see *Figure 4*). One teacher later opted out of implementing the intervention owing to an extended period of sick leave. For school personnel involvement in a semistructured interview or focus group discussion regarding their experiences of taking part in the research (comparison and intervention) following the final follow-up see *Chapter 7*.

Recruitment of pupils, pupil opt-out and retention

Recruitment of 831 pupils to the study at baseline represents an overall pupil recruitment rate of 80.9%. Parental withdrawal of consent accounted for 6.8% of the loss ($n = 70$) and pupil opt-out for 3.1% ($n = 32$). Pupil absence or unavailability at baseline in combination with pupils who chose not to complete the questionnaire or who were unable to because they had not returned consent forms to the research team accounted for the remaining 9% of loss ($n = 94$). In one school a number of pupils indicated that they were unable to participate because they did not have sufficient English to understand the consent form.

In two schools, teachers had forgotten to distribute the information sheets to pupils. They also had not given them any indication that the school was taking part in the research or that data collection was scheduled for that day. Although the researchers made an effort to spend a little more time explaining the research in these two schools, given time constraints there was a limit to the amount of additional information that could be imparted to pupils at this juncture. There was a noticeable difference among pupils who had prior warning and a chance to read the information sheets, both in their questions to the researcher and their expressed satisfaction with taking part.

TABLE 21 Reasons for school participation in this trial

Reasons for school participation	<i>n</i> (%)
Belief that the intervention would be useful to pupils	8 (100)
Credibility of the intervention/research	8 (100)
Desire to improve RSE provision within the school	6 (75)
Compatibility of the intervention with pupil needs (teenage pregnancy a concern)	5 (63)
Positive experiences with previous research	1 (13)
Involvement in research perceived as beneficial for upcoming inspection	1 (13)

As detailed in *Table 22*, pupil participation also varied by school type, with the highest recruitment rates in the three RC schools (> 90%) and the controlled secondary school (92%). The lowest rates were in the controlled grammar school (55%) and one of the integrated schools (62%), both of which had high pupil absentee rates on the day of baseline data collection. The controlled grammar schools' absentee numbers at baseline ($n = 40$) were accounted for by the fact that one class group were undergoing an observation for teacher training purposes and were not permitted to leave their class to take part, while the remaining pupils had to attend a sports event. In the integrated school the absences at baseline ($n = 25$) were accounted for by the fact that data collection took part first thing on a Monday morning when absences were usually higher. Trial champions were provided with questionnaires and consent forms for absent pupils and asked to return them on several occasions before the cut-off point of 23 January. Teachers reported an inability to find time to administer the questionnaires to pupils as the reason for not returning them.

Pupil opt-out rates ranged from 0% to 13% across the schools, with the highest rates in both integrated schools (*Table 22*). Pupils were not asked to give a reason for non-participation. Observations indicated that pupil opt-outs tended to occur in friendship groups (i.e. it was rare for a single young person to opt out; instead, friendship pairs or groups tended to opt out together). In the school with the highest opt-out rate ($n = 17$), pupils had not been provided with the information sheet prior to the study and baseline data collection was scheduled by teachers to immediately follow an exam in a large exam hall, which made providing an overview of the study at a sufficiently loud volume for all students to hear very difficult. In the words of one of the attending teachers, decisions to opt out 'spread like wildfire'.

In another of the schools a teacher told the trial manager after the baseline data collection session that she had had 'around 25' pupils outside the hall prior to the research team's arrival saying that they did not want to take part. The teacher asked them to listen to the explanation of the study prior to deciding. Two pupils opted out following the overview of the study.

Pupil retention rates per school are detailed in *Table 23*.

TABLE 22 Pupil recruitment by school type at baseline

							Voluntary other managed grammar		
Controlled integrated	Grant maintained integrated		Controlled secondary	RC maintained secondary	Controlled grammar	Voluntary RC grammar			All
School ID	10	13 ^a	14	11 ^a	15	12	16	17	–
% pupils eligible for free school meals	32.4	57.4	35.1	48.0	45.5	15.0	8.5	4.0	–
Number of eligible pupils	132	121	91	98	149	123	155	158	1027
Number of parent/guardian withdrawals of consent	12	11	2	2	9	10	6	18	70
Number of pupils opting out	17	10	0	2	2	1	0	0	32
Number absent at baseline	0	24	5	6	2	40	1	16	94
Number recruited	103	76	84	88	136	72	148	124	831
Pupil recruitment rate (%)	78.0	62.8	92.3	89.8	91.3	59.3	95.5	79.1	80.9

^a School recruited from deprived area.

TABLE 23 Percentage change in completion from baseline, to follow-up 1 and follow-up 2 data collection

	School ID	Follow-up 1 questionnaire	Follow-up 2 questionnaire
Intervention	13	51.3% drop	9.2% drop
	15	46.3% drop	8.1% drop
	14	21.4% drop	31.0% drop
	17	8.9% increase	6.5% increase
Comparison	11	3.4% increase	2.3% drop
	16	3.4% drop	2.3% drop
	10	2.9% drop	8.7% drop
	12	12.5% drop	11.1% drop

In the intervention cluster pupil retention was 74.0% by follow-up 1 and 91.4% by follow-up 2. In the comparison cluster, pupil retention was 96.6% by follow-up 1 and 94.9% by follow-up 2. Pupil retention at trial level was 85.2% by follow-up 1 and 93.1% by follow-up 2. The lower follow-up at follow-up 1 was mostly because it occurred too near the holidays when pupils' attendance had already started to drop off.

We originally aimed to recruit 80% of eligible children into the research trial (based on pupil 'opt-in' and allowing for 'opt-out' parental consent). Of the eight schools recruited, there were 1027 eligible pupils in Year 11 who could participate at baseline data collection. (For an overview of pupils responding to the questionnaire at each data collection time point, see *Tables 28 and 29*.) The proportion of eligible pupils (at baseline) who provided questionnaire data was 81% (for both the intervention and control group). At follow-up 1 data collection (allowing for loss of eligible pupils who had moved school or were now being home-schooled), these figures were 60% and 78%, respectively (the reason for this lower return is because we left data collection too close to the summer holidays and many of the pupils were already absent from class). At follow-up 2 data collection (allowing for loss of eligible pupils who had moved school), these figures were 76% and 77%, respectively. At each data collection time point (baseline, follow-up 1 and 2) 97% of pupils who completed the questionnaire answered the questions relating to the main composite primary outcome measure (see *Chapter 6*). At baseline, this involved 803 pupils and at follow-up 2 745 pupils (representing a reduction in numbers of 7%). Of the 803 pupils who answered the main composite primary outcome measure at baseline, 629 (22% drop-out) went on to answer the same questions at follow-up 1 data collection and 699 (13% drop-out) at follow-up 2 data collection (*Tables 24 and 25*).

The trial ended following successful completion of follow-up data collection with all pupils by 30 October 2015.

TABLE 24 Number of questionnaires answered per data collection time point, showing continuity of pupil participation in data collection

Data collection time point	Number of questionnaires answered						
	Baseline only	Baseline and follow-up 1	Baseline and follow-up 2	Baseline, follow-up 1 and follow-up 2	Follow-up 1 only	Follow-up 2 only	Follow-up 1 and follow-up 2
Baseline	39	48	126	618	N/A	N/A	N/A
Follow-up 1 (5 month)	N/A	48	N/A	618	6	N/A	26
Follow-up 2 (9 month)	N/A	N/A	126	618	N/A	2	26
N/A, not applicable.							

TABLE 25 Numbers of questionnaires answered per data collection time point, where pupils completed items relevant to the composite primary outcome measure

Data collection time point	Number of eligible pupils	Number of pupils responding to questionnaire	Number of pupils answering all questionnaire items related to the composite primary outcome measure	Number of pupils answering all questionnaire items related to the composite primary outcome measure at baseline and follow-up 1	Number of pupils answering all questionnaire items related to the composite primary outcome measure at baseline and follow-up 2
Baseline	1027	831	803	629	699
Follow-up 1	1024	698	676	629	N/A
Follow-up 2	1013	772	772	N/A	699
N/A, not applicable.					

Recruitment of parents and parental opt-out

Recruitment of parents and guardians to attend the school-facilitated information and discussion session was extremely low, with an overall recruitment rate of 2.3% (i.e. 9 mothers and one father representing 10 different pupils) assuming potential recruitment of one representative parent or guardian for each eligible pupil in the three intervention schools that held the session ($n = 428$). All three schools chose to run the event in the late afternoon (two schools started at 15:30 and one at 16:30). Reasons for this early start included difficulties keeping the school open late for such an event and a lack of desire on the part of the teachers to stay late themselves. One school did not hold the parents event because the teacher who was responsible for organising and delivering it went on sick leave and failed to 'catch up' on organising it on her return 1 week later.

In the three schools that held the event, parental attendance was extremely low (between one and six parents/guardians attended). Based on experiences of similar events, teachers in two of the schools anticipated that attendance would be very low. One teacher said that 'our parents are not very supportive of their children when it comes to things like this'.

In response to poor attendance at these sessions, recruitment targets were revised. A 6-minute information video was recorded which contained the key points from the information session. This was posted on a locked YouTube channel and parents were sent a link to access it via e-mail or text message. From parents who attended these sessions we aimed to recruit a total of 25 parents to take part in a focus group interview with a researcher. In order to capture the views of those who did not attend the information session or focus groups all parents/guardians were sent a link to a short online survey. It was estimated that 40% of parents would respond to this survey. Parents of pupils in the comparison group were not recruited to the study.

The information session video on the YouTube channel was viewed by 45 parents (12.5%, assuming potential recruitment of one representative parent or guardian for each eligible pupil in the three intervention schools alerted to the online video). Owing to an administrative error, parents in one school did not receive the information video but only a printed copy of the information sheet. This school (school ID 17) had the highest number of parental opt-outs.

In total, 29 parents responded to the parents' survey, representing an 8.3% response rate [all parents whose children were eligible to receive the intervention (eligible pupils minus parental and pupil opt-outs) received the text alerting them to the survey]. In school 17 this figure was reduced to $n = 21$, owing to only one class being able to receive the intervention as a result of teacher sick leave. Of the responding parents, 22 indicated that they had not attended the information and discussion session (see *Chapter 7*).

See *Chapter 7* for more information provided by parents who took part in a semistructured interview or focus group discussion following one of the information sessions.

As indicated in *Table 25*, parental withdrawal of consent rates ranged from 2% to 11% with the lowest rates in one of the RC maintained secondary schools and the controlled secondary ($n = 2$) and the highest in the voluntary other managed grammar ($n = 18$). Most parents did not include a reason, but of those who did ($n = 16$) reasons provided were variations of:

my child does not want to take part ($n = 10$)

I do not want my child to take part ($n = 2$)

my child wants to focus on his/her exam subjects ($n = 1$)

my child is busy with extra-curricular activities ($n = 2$)

my child has a learning disability so I do not think it is appropriate for him to take part ($n = 1$)

At the time of data collection teachers in four of the schools reported that some parents had been in contact with them because they were confused about whether or not to send back the withdrawal of consent form if they were happy for their child to take part. In the voluntary RC grammar school, five parents who had initially opted out contacted the school after their child had received the information sheet to say that they were now happy for their child to take part. Teachers theorised that this may have been at the request of the child but one teacher reported that a parent to whom she had spoken had previously thought that her child was being 'singled out' for participation in the study and when she realised everyone would be taking part she changed her mind.

Discussion

This study allowed analysis of anticipated and unexpected challenges to successful recruitment and retention to inform decisions regarding optimal recruitment and retention strategies for a future Phase III trial.

The study has demonstrated that using RSE training days is a powerful way of recruiting schools to sexual health trials and much more effective than cold-call invitation or approach following introduction. These events offered an opportunity to provide a clear overview of the research and its potential benefits to schools and pupils and, owing to the fact that recruitment presentations took place at statutory events, added to perceptions of its credibility, an important consideration in helping a study stand out from the numerous invitations received by schools. A future full trial should exploit this and other means of recruiting schools, by means of, for example, some of the suggestions made by participants, such as continued provision of and access to the resource. Should recruitment at such events not provide the total number of required schools, a future trial might also consider asking contacts at recruited schools to introduce them to colleagues at other schools who they know might be interested in taking part.

Recruitment targets for schools were met within the planned time frame following some adjustment to the initial sample stratification definitions. The overall recruitment rate of 38% was strongly impacted by the challenges we faced recruiting RC schools and voluntary other managed grammar schools. Although it was anticipated that recruiting RC schools might be difficult, an unexpected caveat was that it was not RC schools in general that were difficult to recruit, but RC grammar schools (recruitment rate: 13% in RC grammar compared with 67% in RC maintained secondary) and other academically focused grammar schools, in particular, voluntary other managed grammars (recruitment rate: 17%). The controlled grammar and voluntary other managed school recruited was strongly influenced by professional networks. The main

reason that the sample was stratified in this way was so that the reach of the intervention could be examined, in particular, its acceptability in RC schools and schools in deprived areas. This stratification would, therefore, not be necessary for a future full trial. Had stratification not been done in this way, in order to recruit schools of different management types, recruitment rates would have been much higher and resources expended on recruitment activities would have been lower.

Although the interaction between religious ethos and intervention content is important, much more influential in terms of potential barriers to recruitment in the current study were perceptions of the relevance of the intervention for the pupils, burden on teachers and pupils and the schools' current and prior involvement in other research. The majority of RC schools that declined to participate did so without knowing anything about the intervention aside from the fact that it was about teenage pregnancy. Similarly, the grammar schools in general who refused to take part indicated as primary reasons a lack of room in the curriculum ('we do not have room for it or we already have a comprehensive RSE programme') and a perceived lack of fit with pupil needs ('we do not have any problems with teenage pregnancy'). We therefore propose that in a future full trial the sample is not stratified by school management type or deprivation, but, rather, that recruitment targets should seek to recruit all schools that express an interest in participating in the study. However, in order to ensure a representative sample, it is still important to ensure that a mix of schools is recruited to a full trial, including grammar and religious schools. We therefore suggest that targeted recruitment, which speaks to the needs of different school types, is vital. For example:

- recruitment presentations and introductory literature should include information about the intervention and emphasise its academic relevance (fit with the statutory RSE curriculum) and innovative nature (targeted at teenage males), and provide more information on the persistent public health problem of teenage pregnancy, which transcends social class and remains problematic for teenagers and their families
- introductory letters could be adapted so that, although all the key messages are included, the emphasis is adapted to different school types (e.g. the academic focus and innovative nature of the intervention is emphasised to grammar schools and so on). A clear outline of the content of the intervention and testimonials from previous users in RC schools might encourage them to look at the intervention prior to deciding that it is not in line with their ethos.

The most common reasons provided for non-participation were a lack of space in the LLW curriculum and prior commitment to other research. Although the intervention was designed to be used within the LLW/PD curriculum, during the study two of the schools delivered it during 'form'/PC and a third during RE classes because teachers felt that it was simpler to fit it within these classes for the purposes of the study. This was not emphasised to schools at the recruitment stage and should be during a full trial. School commitment to other research is an important issue and not something that we can impact greatly in the short term. Planning for a future trial should, however, be cognisant of the amount of invitations that schools receive to participate in research and include innovative ways of ensuring that the invitation actually reaches school decision-makers.

Reasons for schools choosing to participate included a keenness to get involved in more research, the fact that they had had positive experiences with previous research, the fact that the intervention was compatible with needs (teenage pregnancy a current concern for the school), the credibility of the intervention/research (word of mouth), and the fact that involvement in research was perceived as beneficial for upcoming inspections.

Pupil recruitment targets were met, with an overall pupil recruitment rate of 80.9%. Absentees who did not return completed questionnaires accounted for 9% of non-participants, and parental and pupil opt-outs accounted for the remaining 9.9% (6.8% and 3.1%, respectively). Of those parents ($n = 16$) who provided a reason why they had opted their child out, most said that their child did not want to take part or that they did not think their child had time to take part. Although the parental opt-out rate was satisfactory, a number of teachers indicated that they felt that some parents had misunderstood the withdrawal of the

consent form and had returned it because this is what they usually do in order to allow their child to participate in such activities. Indeed, a number of parents wrote on the form that they found it confusing and several sent it back while also indicating that they were happy for their child to take part. A future trial might ensure that data collection documentation is clearer to parents, perhaps involving steering group members in ensuring clarity in this regard. In addition, parents might be given the option of contacting the research team or school co-ordinator via telephone for clarification prior to consenting.

Equally, although pupil opt-out rates were relatively low in the study, it was evident that most withdrew consent because of their dissatisfaction with the fact that they had not been pre-warned about the study or given time to consider whether or not they wanted to take part. In the school in which pupil opt-out was highest, baseline data collection took place immediately after an exam in a large hall (the acoustics of which made it difficult for all pupils to hear the information about the research). Although provided to teachers, pupils had not been given copies of the information sheet prior to data collection. A future trial should ensure that pupils are provided with adequate information about the research prior to data collection. As none of the schools took up the offer of the research fellow providing this on a separate occasion prior to data collection, this might be best achieved by creating a short video that teachers should show to pupils a week or so prior to data collection. Moreover, although data collection in a large hall saves on resources in terms of the numbers of research assistants needed to attend the data collection sessions, we found that, in most cases, it was not an appropriate option for recruitment or ensuring data quality. In two of the three schools that chose this option, pupils were more likely to chat to each other during completion. Furthermore, when pupils decided that they did not want to take part, this generally resulted in several pupils in the same physical area deciding not to take part and these pupils then caused disruption to those who were taking part. All follow-up data collection in the current study was conducted in small class groups (apart from in one school in which teacher control of the year group was exceptionally high). This is recommended for a future trial.

When large numbers of absentee questionnaires were left for teachers they struggled to return to them, indicating that it was difficult to find time to collect data from these pupils within the already busy school schedule. A future trial might attempt to minimise the number of absentees by ensuring that data collection does not take place at a time when absences are more likely (e.g. Monday mornings and Friday afternoons). Equally, when there are large numbers of absentees, researchers might offer to facilitate supervision and distribution of these at a particular time so as to encourage completion and ease the burden on the teacher.

Although the core part of this intervention is a teacher-delivered intervention to pupils, additional communication to involve parents also featured in the logic model of the intervention. We failed to reach the proposed target of recruiting one parent/guardian representative for 50% of participating pupils to attend the parents' information and discussion session. Co-ordinators in all the intervention schools indicated that parents were difficult to engage in general (see *Chapter 7*). Some indicated that this was due to a lack of interest on the part of the parents, whereas others noted factors such as the distance parents lived from the school (in some rural schools as far as 30 miles) and possible difficulties they had with transport or child-minding for younger children or being unable to get time off work to attend. Often reported predictors of parental attendance include sociodemographic variables such as education and income level, which may be related to resources and ability to attend.^{117–120} A future trial might consider providing parents with incentives in order to attend, including funds for travel or child-minding.

As with schools, researchers have found that parents who perceive that the programme may help address their children's problems are more likely to engage.¹¹⁷ Given the importance attached to ensuring that schools and parents are aware of the importance of speaking to their children about such issues, a future trial might consider developing a short video for parents to explain the significance of helping teenagers avoid teenage pregnancy and the impact that an UTP might have on their lives.

Alternatively, some teachers also suggested that the topic of teenage pregnancy might be a challenging one, especially in areas in which parents themselves had experienced an UTP. One teacher suggested that parents might have been afraid that teachers would 'judge' them if they came to the session and, in focus groups, several pupils indicated that their parents refused to do the parent/pupil homework exercise with them because they felt it would be 'hypocritical' to advise them about teenage pregnancy when they had been teenage parents themselves. This is unlikely to be a universal perception, however, and it is worth noting that one mother who attended a parents' focus group said that the very reason she had attended was because she had experienced teenage pregnancy herself and she wanted to ensure her children waited until they were older. A future trial should ensure that the non-judgemental nature of the intervention in general and in the parents' session in particular is communicated to parents. Another option, used by Harrington *et al.*¹¹⁵ to recruit hard to reach populations, was explanatory telephone calls to parents to successfully increase participation. A future trial might consider this option.

In addition, cultural differences in attitudes towards sex education programmes, problems reading or comprehending the consent form, information sheet and letter of invitation may all have contributed to a lack of engagement. This may have been a particular problem in one school that has an ethnic minority population of 20%. A future trial should cost for translation services and might also involve ethnic minority parents in this process.

Although we had modest success with the YouTube video, it was in fact much more successful than inviting parents to attend the session. Haggerty *et al.*¹²⁰ compared attendance at a parenting workshop with participation in a self-administered version of the same programme. They found that older child age and higher levels of parent education strongly predicted engagement with the self-administered version of the intervention. A future trial might develop and examine the value of this methodology further, for example, by creating a more engaging video such as animation or similar.

The main reasons for participation were that schools were keen to get involved in more research, that they had had positive experiences with previous research, that the intervention was compatible with needs (teenage pregnancy was a current concern), the credibility of the intervention/research (word of mouth), and involvement in research was perceived as beneficial for upcoming inspection. It was agreed by principals that in a future trial, or trials in general, monetary incentives are important. However, monetary incentives would, they argued, work only in the context of the social value of the research itself and if the benefits to the participants had a positive impact on school recruitment. The small incentives provided to staff and pupils were, however, greatly appreciated. They were presented as a 'thank you' for time and effort and, as such, went some way towards helping maintain positive relationships with participants.

All schools were retained in the trial and the pupil retention rate was mainly attributed to the provision of clear information from the beginning and continuous contact with schools at meaningful points in time.

Conclusions

In relation to recruitment, the feasibility study demonstrated that our target aim of recruiting seven schools, four to the intervention arm and three to the control arm, was realistic and demonstrated that we could achieve our school recruitment target rate (target of 25%, achieved 37%). The study also demonstrated that it was feasible to recruit the full range of the most common types of schools in NI, namely in terms of the differing school management types, including faith-based schools, schools that are especially academically oriented and those that are not, and schools that are in socially deprived as well as socially affluent areas. This was important because we believe that this is the first RSE intervention trial to include faith-based schools in the UK and > 50% of schools in NI are faith-based schools. Nonetheless, we learned that the hardest schools to recruit for this trial were schools that were both faith based (RC) and high academic achieving schools. These are what are known as 'Catholic Grammar Schools' in NI.

Overall, we learned some valuable lessons about how to recruit for our next trial. RSE training days for teachers, facilitated by statutory agencies – in our case the PHA – were especially successful. In addition, in order to recruit schools across the socioeconomic and management spectrum, we recommend having tailored recruitment materials, for example tailored letters, that speak to the needs of different schools, and including testimonials from others, perhaps those drawn from a feasibility trial. Financial incentives and ensuring that the letters reach the decision-makers in schools are also important considerations for future recruitment strategies.

Pupil recruitment targets within the school were met (target of 80% pupil recruitment, achieved 80.1%). Approximately 9% of this was due to absentee pupils at baseline and 10% was due to refusal to consent to study. We aim to make parental opt-out consent processes clearer in the full effectiveness trial. Parental recruitment strategies to information evenings for intervention and follow-up focus groups failed very badly. Parental recruitment to the intervention (parental information sessions) failed, achieving only 2.3% of all parents/guardians. Consequently, recruitment of parents to focus group interviews also failed, as it was planned to recruit parents through the information session. Following more detailed research with parents and consultation on this topic, it has been decided to change the intervention component for parents to an online delivery method. Separate research funding has been obtained to deliver this change. We would still recommend pursuing a smaller amount of focus group interviews with parents in the next trial, but, overall, we shall rely more heavily on online survey data collection methods for parents. Recruitment of teachers for semistructured interviews within schools was unproblematic.

Randomisation processes proved successful, with no issues to report. Retention of schools was successful (100%) as was retention of pupils (93.1%). However, we learned the importance of developing a connection with the trial champion in schools and, in many cases, the school principal (head teacher) or VP, of staying in touch with schools and of not doing data collection with pupils too near the summer breaks when absenteeism is high.

Chapter 6 Quantitative results

Introduction

Unprotected sex during teenage years is well established as the main proximate behavioural determinant of teenage pregnancy and is a commonly measured behavioural outcome in studies examining the impact of RSE interventions on teenage pregnancy.^{16,18,121–123} Studies indicate that, although other behavioural determinants (such as frequency of sexual intercourse and number of sexual partners) are important, avoidance of unprotected sex via consistent use of contraception is central in explaining variation in levels of teenage pregnancy.^{22,124} A reduction in UTP rates would be the ideal primary outcome measure. However, the sample size would need to be very large in order to detect change in relation to this. In addition, teenage conception rates are not routinely collected in NI health and social care data, although teenage births are. In this study it was intended to pilot the acceptability of collecting a surrogate proximate behavioural determinant associated with UTP, namely having had unprotected sex, from pupils within schools within this age group (aged 14–15 years).

Secondary outcomes informed by our theory of change model (see *Chapter 3*) include knowledge, attitudes, skills and intentions relating to avoiding UTP. These short-term impacts are hypothesised to lead to increased intention to avoid UTP.^{40,125–127} In this feasibility trial, data were collected using a number of standardised measures chosen because the constructs that they measure map closely to the theoretical framework underpinning the intervention (see *Chapter 4*). For these analyses, we were interested in how the results are differentiated between males and females and in relation to SES. In addition, to assist with the economic evaluation model to be used in a Phase III effectiveness trial, additional secondary outcomes were frequency of engagement in sexual intercourse, contraception use and diagnosis of STIs.

We have summarised the main quantitative findings of the study in a report format specifically tailored to the interests of both participating pupils and schools and are about to embark on disseminating this to participant schools (pending the return of the trial manager from maternity leave, as she has the strongest relationship with participating schools, and will deliver the reports in person). For both the pupil and school report, see *Appendix 9*.

For an overview of the integration of the quantitative component of the feasibility study, see *Appendix 9*.

Methods

The main purpose of the statistical analysis was to assess the feasibility and acceptability of the measures used. A detailed statistical analysis plan was written prior to analysis. The reporting and presentation of findings are in accordance with the CONSORT guidelines for cluster RCTs.¹²⁸ Primary analyses were on an intention-to-treat (ITT) basis, using all participants with complete data for baseline and follow-up, in the groups to which they were randomised. In intervention schools, all trial participants' data were included in the analyses, regardless of the extent of their engagement with the programme. In all tables the means [standard deviations (SDs)] are presented for continuous variables and the overall mean is presented with standard error (SE) adjusted for the eight clusters (schools). Number (%) is presented for all categorical variables for those pupils who answered the questions. The *p*-values in the tables are indicative only and should not be interpreted as a definitive result. The 95% confidence intervals are more useful to interpret the data at this stage, to inform variance in the outcome results rather than the use of inferential statistics.

Appropriate descriptive summaries of baseline demographic and questionnaire data for pupils and from the two study groups were tabulated and descriptive summaries produced for baseline data at cluster level,

where appropriate questionnaire data relating to pupil outcomes (at 5- and 9-month follow-up) were analysed using frequencies and descriptive statistics using Stata® 2013 (StataCorp LP, College Station, TX, USA) or IBM Statistical Product and Service Solutions Statistics for Windows, Version 20.0 (IBM Corp, Armonk, NY, USA). Differences between the trial groups for all the outcomes are reported using descriptive statistics. Factors that may influence outcomes such as sex (male/female), social class and religiosity were also explored.

Results

Baseline characteristics of participating pupils

In total, 831 Year 11 pupils aged between 14 and 16 years took part in the baseline evaluation. Just < 50% (49.5%) were female and just > 50% (50.5%) were male. Overall, 420 pupils were randomly allocated to the intervention group and 411 to the control group (see *Chapter 5* for the randomisation process). *Table 26* shows the breakdown of the sample by sex and group allocation.

Table 27 shows the baseline demographic characteristics of the sample. This shows that the mean age was 14.4 years (SE = 0.019) in both the intervention and control groups. The ethnicity of the majority of participants

TABLE 26 Pupil sample characteristics by sex and group allocation

Sex	Intervention	Control	Total, <i>n</i> (%)
Female	190	208	398 (47.9)
Male	230	203	433 (52.1)
Total, <i>n</i> (%)	420 (50.5)	411 (49.5)	831 (100)

TABLE 27 Baseline characteristics of the sample by treatment arm^a

Characteristic	Intervention	Missing data	Control	Missing data
Mean age, years (SE)	14.4 (0.019)		14.5 (0.012)	
Ethnicity, <i>n</i> (%)		4 (1)		4 (1)
White	392 (93.3)		391 (95.1)	
Chinese	2 (0.5)		6 (1.5)	
Irish Traveller	3 (0.7)		4 (1)	
Other	19 (4.5)		6 (1.5)	
Religiosity, <i>n</i> (%)		2 (0.5)		3 (0.7)
Very	31 (7.4)		45 (10.9)	
Fairly	155 (36.9)		191 (46.5)	
Not very	174 (41.4)		107 (26.0)	
Not at all	58 (13.8)		65 (15.8)	
Religion, <i>n</i> (%)		2 (0.5)		8 (1.9)
None	25 (6.0)		24 (5.8)	
Catholic	183 (43.6)		239 (58.2)	
Protestant	181 (43.1)		126 (30.7)	
Muslim	4 (1.0)		1 (0.2)	
Mixed	7 (1.7)		4 (1.0)	
Other	18 (4.3)		9 (2.2)	

TABLE 27 Baseline characteristics of the sample by treatment arm^a (*continued*)

Characteristic	Intervention	Missing data	Control	Missing data
Do you get free school meals?, <i>n</i> (%)		1 (0.2)		7 (1.7)
Yes	135 (32.1)		87 (21.2)	
No	264 (62.9)		312 (75.9)	
Do not know	20 (4.8)		5 (1.2)	
Mother highest level of education, <i>n</i> (%)		283 (67.4)		268 (65.2)
Primary school	3 (0.7)		2 (0.5)	
GCSE/O level or equivalent	84 (20)		95 (23.1)	
A level or equivalent	48 (11.4)		44 (10.7)	
Apprenticeship (e.g. plumber)	2 (0.5)		2 (0.5)	
Certificate or diploma	15 (1.9)		18 (2.3)	
University degree	93 (11.6)		112 (14.0)	
None	3 (0.4)		1 (0.1)	
Do not know	147 (18.4)		125 (15.6)	
Not applicable	3 (0.4)		4 (0.5)	
Father highest level of education, <i>n</i> (%)		21 (5)		7 (1.7)
Primary school	8 (1.9)		12 (2.9)	
GCSE/O level or equivalent	72 (17.1)		106 (25.8)	
A level or equivalent	36 (8.6)		29 (7.1)	
Apprenticeship (e.g. plumber)	26 (6.2)		25 (6.1)	
Certificate or diploma	14 (3.3)		15 (3.6)	
University degree	89 (21.2)		74 (18.0)	
None	3 (0.7)		9 (2.2)	
Do not know	149 (35.5)		127 (30.9)	
Not applicable	2 (0.5)		7 (1.7)	
Future aspirations, <i>n</i> (%)		4 (1.0)		8 (1.9)
At college/uni full-time	63 (15)		46 (11.2)	
At college/uni and working part-time	32 (7.6)		54 (13.1)	
Working full-time	186 (44.3)		180 (43.8)	
Working part-time	106 (25.2)		90 (21.9)	
On a training scheme	15 (3.6)		19 (4.6)	
Unemployed	4 (1.0)		1 (0.2)	
Other	10 (2.4)		13 (3.2)	
Sexuality, <i>n</i> (%)		25 (6.0)		12 (2.9)
I've never felt sexually attracted to anyone	45 (10.7)		30 (7.3)	
Only to male, and never to females	133 (31.7)		166 (40.4)	
More often to males and at least once to a female	9 (2.1)		10 (2.4)	
About equally often to females and to males	3 (0.7)		6 (1.5)	
More often to females and at least once to a male	1 (0.2)		3 (0.7)	
Only to females, never to males	204 (48.6)		184 (44.8)	

O level, Ordinary level.

^a Data are number (%) of questionnaires returned at baseline: 420 for intervention, 411 for control or mean (SE).

was white (British/Irish) and the next largest group was Chinese (8% in total). For those whose ethnicity fell into the 'other' category, the most commonly cited ethnicity was Polish. In terms of religion, a wide range of religions was listed, with the most common being Christian, Atheist and Mormon. The most common religion in the sample was Catholic ($n = 422$, 50.8%). The second most common was Protestant ($n = 307$, 36.9%). The majority (41.6%) of pupils in the intervention group identified themselves as 'not very religious', whereas the control group (46.8%) most commonly identified themselves as 'fairly religious'. Most of the pupils were not in receipt of free school meals; however, a slightly larger proportion in intervention schools were obtaining free school meals (16.4% vs. 10.6% in control schools). Here, we also present two measures of SES, one of which is based on parental highest level of education and one of which is based on children's future educational aspirations (for further discussion on the issues encountered relating to a measure of SES, see *Chapter 4*).

Stopping rules/discontinuation criteria

The following were the trial stopping/discontinuation criteria as documented in the study protocol.

1. We shall monitor for harm by examining outcome data as soon as possible after each follow-up. If deterioration in scores indicated in the outcome measures in the intervention group are not matched by deterioration in scores in the control group, we would consider stopping the intervention.

Results

- At follow-up 1 we found no evidence of harm and the ongoing process evaluation also indicated an overall positive evaluation among users.
- Results at follow-up 1 (5 months post implementation) indicated that there was no significant difference between the two groups (intervention and control) at baseline for the primary outcome (abstinence or protected sex) ($p = 0.45$) or at 5-month follow-up ($p = 0.80$). However, the intervention group showed a small non-significant increase (improvement) in proportions across time of 0.6% compared with a worsening/deterioration of 2% in the control group. These results are noted in detail below in the reportage of the results of the primary outcome.
- Thus the trial continued to completion to follow-up 2 and ended on completion of data collection by 30 October 2015.

Defining primary and secondary outcomes

Primary outcome

The surrogate measures (alternatives to the use of teenage pregnancy) used in this feasibility study to create the composite primary outcome measure were abstinence from sexual intercourse (delay in initiation of sex or return to abstinence) or avoidance of unprotected sexual intercourse (consistent correct use of contraception that does not include withdrawal or natural family planning). In this trial we used a number of questionnaire items to obtain this outcome (for the full questionnaire, see *Appendix 3*).

At baseline, follow-up 1 and follow-up 2, the delay of initiation of sex was determined using the following questionnaire item.

- Have you ever experienced penetrative sex (penis–vagina) with another person?
 - Yes
 - No

At follow-up 1 data collection, a return to abstinence was determined using the following questionnaire item. If pupils responded more than 5 months ago, they had abstained since baseline. (In some schools follow-up 1 took place 6 months post baseline. If this was the case the question was changed to reflect this.)

- When was the last time you had penetrative sex with someone?
 - Less than 1 week ago.
 - More than 1 week but less than 1 month ago.
 - 1–4 months ago.
 - More than 5 months ago (*when baseline data collection occurred*).

At follow-up 2 data collection, a return to abstinence was determined using the following questionnaire item. If pupils responded that they had not had sex since June 2015, they had abstained for the past 4 months.

- How many times have you had penetrative sex since you completed the last questionnaire in June 2015? (*which was 4 months prior*)
 - Not since June 2015.
 - Once.
 - Between two and five times.
 - Between six and 10 times.
 - Between 11 and 20 times.
 - More than 20 times.

Avoidance of unprotected sexual intercourse (consistent correct use of contraception that does not include withdrawal or natural family planning) was determined using the following two questionnaire items.

- Thinking about ALL the times you have had sex EVER. How often were you or your partner protected against pregnancy? (Do not count the withdrawal method or emergency contraception – ‘the morning after pill’).
 - Never.
 - Not very often.
 - About half the time.
 - Most of the time.
 - Always.
- The last time you had penetrative sex, did you or your partner use any form of contraception?
 - None for me, do not know about partner.
 - None for either of us.
 - Yes.
- If yes, please tick all the contraceptives that you used the last time you had sex: Type:
 - Pill, patch or vaginal ring.
 - Condoms.
 - Emergency contraceptive pill.
 - Injection.
 - Implant.
 - Withdrawal method.
 - Intrauterine device.
 - Diaphragm/cap/spermicide.
 - Natural family planning.
 - Do not know name.
 - Other.

In the feasibility study, 91.5% of responding pupils in the four intervention schools and 93.6% of pupils in the four control schools reported that they had not yet had penetrative sex at baseline. At follow-up 1 this reduced to 91.3% and 89.4%, and at follow-up 2 to 84.1% and 87.5% for intervention schools and control schools, respectively. Pupil responses to the questionnaire items that were designed to determine abstinence are detailed in *Table 28*.

Sexually active respondents varied in their use of contraception/protection. Contraception types reported included the pill, patch or vaginal ring, condoms, emergency contraceptive pill, injection, implant, intrauterine devices, diaphragms/caps/spermicides, withdrawal and natural family planning. Condom use was the most common method of contraceptive used. Pupils reporting the withdrawal method and the natural family planning method (5% at baseline, 17% at follow-up 1, 5% at follow-up 2) were recorded into the results as not having used contraception (i.e. as having had unprotected sex). Pupil responses to withdrawal and natural family planning methods as forms of contraceptive are presented in *Table 29*.

Contraceptive use components of the composite primary outcome are detailed in *Table 30*.

The primary composite outcome measure – abstinence or protected sex – is detailed in *Table 31*.

There was no significant difference between the two groups at baseline for the composite outcome abstinence or protected sex including withdrawal/natural method ($p = 0.45$) or at 5- ($p = 0.80$) or 9-month follow-up ($p = 0.91$).

In the feasibility study, approximately 3% of our sample reported unprotected sex at baseline (3.6% intervention and 2.5% control) and approximately 5% reported unprotected sex at follow-up 2 (5.4% intervention and 5.6% control). This amounted to a 50% increase in unprotected sex by follow-up 2 in the

TABLE 28 Frequency of penetrative sex

Overall (schools combined)	Baseline		Follow-up 1		Follow-up 2	
	Intervention	Control	Intervention	Control	Intervention	Control
<i>Have you ever experienced penetrative sex with another person?</i>						
Yes, <i>n</i> (%)	35 (8.5)	25 (6.4)	26 (8.7)	40 (10.6)	59 (16.0)	47 (12.5)
No, <i>n</i> (%)	376 (91.5)	367 (93.6)	273 (91.3)	338 (89.4)	311 (84.1)	328 (87.5)
<i>When was the last time you had penetrative sex with someone?</i>						
More than 5 months ago (follow-up 1)						
<i>How many times have you had penetrative sex since you completed the last questionnaire in June 2015?</i>						
Not since June 2015 (follow-up 2)						

TABLE 29 Pupils reporting the withdrawal and natural family planning methods as forms of contraceptive

Method	Baseline		Follow-up 1		Follow-up 2	
	Intervention	Control	Intervention	Control	Intervention	Control
Withdrawal, <i>n</i> (%)	2 (6.7)	0 (0)	2 (8.3)	7 (12.1)	0 (0)	5 (12.5)
Natural, <i>n</i> (%)	0 (0)	1 (4.8)	0 (0)	2 (3.4)	0 (0)	0 (0)

TABLE 30 Contraceptive use

Overall (schools combined)	Baseline		Follow-up 1		Follow-up 2	
	Intervention	Control	Intervention	Control	Intervention	Control
How often protected?, n (%)						
Never	5 (14.7)	3 (13.0)	5 (19.2)	8 (20.0)	15 (27.3)	8 (19.1)
Not very often	4 (11.8)	4 (17.4)	3 (11.5)	9 (22.5)	4 (7.3)	1 (2.4)
About half the time	3 (8.8)	0 (0.0)	1 (3.9)	4 (10.0)	3 (5.5)	7 (16.7)
Most of the time	3 (8.8)	6 (26.1)	2 (7.7)	7 (17.5)	12 (21.8)	10 (23.8)
Always	19 (55.9)	10 (43.5)	15 (57.7)	12 (30.0)	21 (38.2)	16 (38.1)
Use of contraception when you last had sex?, n (%)						
None for me, do not know about partner	8 (22.9)	3 (12.0)	5 (19.2)	4 (10.5)	7 (13.7)	4 (10.0)
None for either of us	5 (14.3)	6 (24.0)	5 (19.2)	8 (21.1)	10 (19.6)	9 (22.5)
Yes	22 (62.9)	16 (64.0)	16 (61.5)	26 (68.4)	34 (66.7)	27 (67.5)

TABLE 31 Primary composite outcome measure – abstinence or protected sex

Outcome measure	Intervention			Control		
	Baseline (n = 411)	5 months (n = 299)	9 months (n = 370)	Baseline (n = 392)	5 months (n = 377)	9 months (n = 375)
Abstinence or protected sex (yes), %	96.8	97.7	96.2	97.7	97.4	97.3
Change from baseline		0.9% (improvement)	–0.6% (deterioration)		–0.3% (deterioration)	–0.4% (deterioration)
Abstinence or protected sex (yes), excluding withdrawal/natural family planning as unprotected, % (95% CI)	96.4 (94.5 to 98.2)	97.0 (95.1 to 98.9)	94.6 (92.3 to 96.9)	97.5 (95.9 to 99.0)	95.5 (93.4 to 97.6)	94.4 (95 92.1 to 96.7)
Change from baseline		0.6% (improvement)	–1.8% (deterioration)		–2.0% (deterioration)	–3.1% (deterioration)

intervention group (3.6% at baseline, rising to 5.4% at follow-up 2) compared with a more than doubling of unprotected sex by follow-up 2 in the control group (2.5% at baseline, rising to 5.6% at follow-up 2).

Subgroup analysis of primary outcome measure by gender

In the subgroup analysis of the primary outcome measure (*Tables 32 and 33*) by gender, there was an improvement in boys in the intervention arm (2.2% improvement at follow-up 1 and 0.5% improvement at follow-up 2) but a deterioration in females in the intervention arm was evident (1.3% deterioration at follow-up 1 and 4.4% deterioration at follow-up 2).

Secondary outcomes

The following secondary outcomes were drawn from the theoretical framework underpinning the intervention (theory of planned behaviour; see *Chapter 3*). To measure these outcomes we used some existing measures with robust reliability and validity (see *Appendix 1*). The baseline questionnaire is included in *Appendix 2*.

TABLE 32 Subgroup analysis for gender and the primary outcome measure, abstinence/protected sex (female)

Outcome measure	Intervention			Control		
	Baseline (n = 186)	5 months (n = 140)	9 months (n = 182)	Baseline (n = 201)	5 months (n = 195)	9 months (n = 190)
Abstinence or protected sex (yes), % (95% CI)	98.4 (96.6 to 100.2)	97.9 (95.5 to 100.3)	96.1 (93.2 to 98.9)	99.0 (97.6 to 100.4)	98.5 (96.7 to 100.2)	98.9 (97.4 to 100.4)
Change from baseline		0.5% (deterioration)	2.3% (deterioration)		0.5% (deterioration)	0.1% (deterioration)
Abstinence or protected sex (yes) excluding withdrawal/natural family planning as unprotected, % (95% CI)	98.4 (96.6 to 100.2)	97.1 (94.4 to 99.9)	94.0 (90.5 to 97.4)	99.0 (97.6 to 100.4)	96.9 (94.5 to 99.3)	94.2 (90.9 to 97.5)
Change from baseline		1.3% (deterioration)	4.4% (deterioration)		2.1% (deterioration)	4.8% (deterioration)

Numbers based on abstinence or protected sex (yes), including withdrawal/natural family planning as unprotected.

TABLE 33 Subgroup analysis for gender and the primary outcome measure, abstinence/protected sex (male)

Outcome measure	Intervention			Control		
	Baseline (n = 225)	5 months (n = 159)	9 months (n = 188)	Baseline (n = 191)	5 months (n = 182)	9 months (n = 185)
Abstinence or protected sex (yes), % (95% CI)	95.6 (92.9 to 98.2)	97.5 (95.1 to 99.9)	96.2 (93.5 to 99.0)	96.3 (93.7 to 99.0)	96.2 (93.4 to 98.9)	95.7 (92.7 to 98.6)
Change from baseline		1.9% (improvement)	0.6% (improvement)		0.1% (deterioration)	0.6% (deterioration)
Abstinence or protected sex (yes) excluding withdrawal/natural family planning as unprotected, % (95% CI)	94.7 (91.7 to 97.6)	96.9 (94.1 to 99.6)	95.2 (92.2 to 98.3)	95.8 (93.0 to 98.7)	94.0 (90.5 to 97.4)	94.6 (91.3 to 97.9)
Change from baseline		2.2% (improvement)	0.5% (improvement)		1.8% (deterioration)	1.2% (deterioration)

Numbers based on abstinence or protected sex (yes), including withdrawal/natural family planning as unprotected.

The first outcome chosen in this questionnaire was Knowledge. The purpose of this was to determine if pupils had increased knowledge about UTP. Knowledge scores represented the total score on the Knowledge scale (Q.15) and the sum of correct answers to the following questionnaire items:

Q.16 What is the legal age of consent (the age at which you can legally first have sex) in NI?

Q.17 Can you think of any health services, clinics or places you could visit if you wanted to get the following? Free Contraception; advice on sexual health (e.g. pregnancy, STIs).

Q.18 Can you think of any websites which provide information on sexual health, relationships and pregnancy?

The second outcome, Attitudes, aimed to determine if pupils:

- had increased awareness that men and women have roles and responsibilities in avoiding UTP;
- hold less stereotypical gender-related attitudes and have increased perception that most peers are not sexually active and use contraception when they are;
- have increased perception that both parents (parent/child communication) and peers support abstinence and/or use of contraception.

Scores resulted from the incorporation of one questionnaire item (Q.19; *Box 2*), and the Comfort Communicating about Pregnancy scale (Q.20), the Comfort Communicating about Contraception scale (Q.20), the Male Role Attitudes scale (Q.22).

The third outcome, Skills, aimed to determine if pupils had increased self-efficacy in communicating about UTP and avoiding UTP. Scores resulted from the incorporation of the Sexual Self-Efficacy scale (Q.21) the Sexual Socialisation scale (Q.23), the Sexual Socialisation Peer subscale (Q.23) and Sexual Socialisation Parent subscale (Q.23).

The final outcome, Intentions, aimed to determine if pupils had higher anticipated regret about UTP and increased strength of intention to avoid UTP. For this construct, the questionnaire incorporated a measure of intention to avoid UTP, developed as part of the research process (see *Chapter 4*). Scores incorporated the Intentions scale, Intentions Self-Efficacy subscale, Intentions Attitudes subscale and the Intentions Norms subscale.

Descriptive statistics for the secondary outcomes are presented below (*Tables 34–36*). As the study was not powered to detect statistically significant differences between groups, we have not conducted mediation analysis or logistic regression to test the impact of these variables on the primary outcome measure.

Compared with pupils in the control group, pupils in the intervention group had more of an increase in knowledge (Knowledge scale score) about UTP at follow-up 1 [0.21 (95% CI –0.14 to 0.55)] and at follow-up 2 [0.15 (95% CI –0.19 to 0.48)]. When asked about the legal age of consent (the age at which you can legally first have sex) in NI, 65.5% of respondents answered with the correct age of 16 years. Thirty-eight per cent of pupils correctly identified a health service, clinic or place where one could obtain free contraception [e.g. GP surgeries, Brook clinics (Brook Young People, Liverpool, UK)] and 40% were able to name a source of advice on sexual health (e.g. GP surgeries, sexual health clinics, internet). Pupils listed a wide variety of websites that

BOX 2 Question 19: Whose responsibility is it to prevent unintended pregnancy?

Put an X on the line below to show how much responsibility you think boys and girls should have. For example, if you think girls should have more responsibility than boys, put an X on the line closer to girl; if you think boys should have more responsibility than girls, put an X on the line closer to boy; If you think boys and girls should have equal responsibility, put an X in the middle of the line.

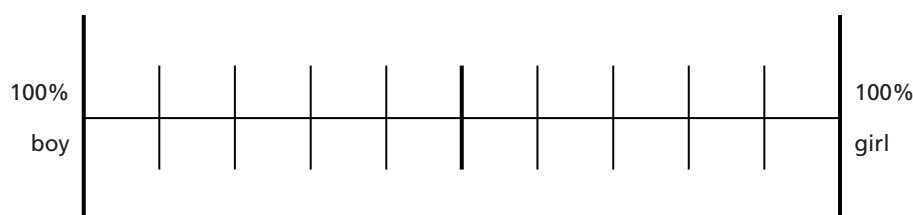


TABLE 34 Secondary outcomes from logic model

Outcome measure	Follow-up 1			Follow-up 2				
	Intervention, Mean \pm SD change	Control, Mean \pm SD change	Difference mean change scores (95% CI)	p-value	Intervention, Mean \pm SD change	Control, Mean \pm SD change	Difference mean change scores (95% CI)	p-value
Knowledge								
Knowledge	0.81 \pm 2.29 (n = 269)	0.60 \pm 2.09 (n = 356)	0.21 (-0.14 to 0.55)	0.24	1.03 \pm 2.36 (n = 324)	0.88 \pm 2.16 (n = 370)	0.15 (-0.19 to 0.48)	0.39
Attitudes								
Comfort communicating about pregnancy	0.12 \pm 1.62 (n = 251)	0.06 \pm 1.69 (n = 341)	0.06 (-0.21 to 0.34)	0.64	0.53 \pm 1.58 (n = 322)	0.57 \pm 1.56 (n = 345)	-0.04 (-0.28 to 0.20)	0.76
Comfort communicating about contraception	0.31 \pm 2.02 (n = 229)	0.23 \pm 2.23 (n = 314)	0.08 (-0.29 to 0.45)	0.67	0.83 \pm 2.21 (n = 275)	0.87 \pm 2.12 (n = 312)	-0.03 (-0.38 to 0.32)	0.86
Male role attitudes	-0.74 \pm 3.42 (n = 220)	-0.19 \pm 4.46 (n = 286)	-0.55 (-1.26 to 0.16)	0.13	-0.65 \pm 3.71 (n = 263)	-1.52 \pm 2.91 (n = 296)	0.87 (0.32 to 1.42)	0.002
Skills								
Sexual self-efficacy	0.18 \pm 1.07 (n = 173)	0.22 \pm 1.16 (n = 219)	-0.04 (-0.26 to 0.19)	0.74	0.25 \pm 1.23 (n = 206)	0.27 \pm 1.19 (n = 236)	-0.01 (-0.24 to 0.22)	0.92
Sexual socialisation	0.06 \pm 7.62 (n = 203)	0.84 \pm 7.50 (n = 283)	-0.78 (-2.14 to 0.58)	0.26	0.36 \pm 7.81 (n = 255)	-0.48 \pm 7.26 n = 294	0.84 (-0.43 to 2.10)	0.19
Sexual socialisation peer subscale	0.17 \pm 5.35 (n = 221)	0.35 \pm 5.41 (n = 308)	-0.18 (-1.11 to 0.75)	0.70	0.38 \pm 5.89 (n = 276)	0.15 \pm 5.64 (n = 317)	0.23 (-0.70 to 1.16)	0.62
Sexual socialisation parent subscale	-0.61 \pm 3.85 (n = 228)	0.33 \pm 3.77 (n = 306)	-0.39 (-1.04 to 0.26)	0.24	-0.02 \pm 4.03 (n = 285)	-0.63 \pm 3.54 (n = 312)	0.61 (-0.001 to 1.22)	0.05

Outcome measure	Follow-up 1				Follow-up 2			
	Intervention, Mean \pm SD change	Control, Mean \pm SD change	Difference mean change scores (95% CI)	p-value	Intervention, Mean \pm SD change	Control, Mean \pm SD change	Difference mean change scores (95% CI)	p-value
Intentions								
Intentions	0.15 \pm 6.93 (n = 216)	0.67 \pm 8.09 (n = 300)	-0.51 (-1.85 to 0.82)	0.45	1.12 \pm 7.93 (n = 261)	1.68 \pm 6.94 (n = 313)	-0.56 (-1.78 to 0.65)	0.36
Intentions self-efficacy subscale	0.65 \pm 3.17 (n = 239)	0.39 \pm 3.75 (n = 338)	0.26 (-0.33 to 0.84)	0.39	0.98 \pm 3.63 (n = 296)	0.87 \pm 3.62 (n = 349)	0.11 (-0.45 to 0.67)	0.70
Intentions attitudes subscale	-0.09 \pm 2.25 (n = 251)	-0.16 \pm 2.53 (n = 342)	0.07 (-0.32 to 0.46)	0.73	0.15 \pm 2.25 (n = 312)	0.07 \pm 2.11 (n = 348)	0.08 (-0.25 to 0.41)	0.64
Intentions norms subscale	-0.28 \pm 4.22 (n = 249)	0.14 \pm 4.63 (n = 339)	-0.42 (-1.15 to 0.31)	0.26	0.06 \pm 4.62 (n = 301)	0.68 \pm 4.14 (n = 343)	-0.62 (-1.29 to 0.06)	0.07

TABLE 35 Secondary outcomes from logic model: female

Outcome measure	Follow-up 1			Follow-up 2				
	Intervention, Mean \pm SD change	Control, Mean \pm SD change	Difference mean change scores (95% CI)	p-value	Intervention, Mean \pm SD change	Control, Mean \pm SD change	Difference mean change scores (95% CI)	p-value
Knowledge								
Knowledge	1.06 \pm 2.40 (n = 125)	0.70 \pm 2.06 (n = 181)	0.36 (−0.14 to 0.87)	0.16	1.43 \pm 2.29 (n = 157)	1.04 \pm 2.10 (n = 187)	0.39 (−0.08 to 0.85)	0.10
Attitudes								
Comfort communicating about pregnancy	−0.03 \pm 1.56 (n = 119)	0.08 \pm 1.63 (n = 179)	−0.11 (−0.48 to 0.26)	0.56	0.48 \pm 1.51 (n = 160)	0.61 \pm 1.55 (n = 180)	−0.12 (−0.45 to 0.20)	0.46
Comfort communicating about contraception	0.10 \pm 1.99 (n = 105)	0.31 \pm 2.17 (n = 160)	−0.21 (−0.73 to 0.31)	0.43	0.80 \pm 2.15 (n = 132)	0.78 \pm 2.03 (n = 156)	0.01 (−0.47 to 0.50)	0.96
Male role attitudes	−1.03 \pm 3.20 (n = 115)	−0.30 \pm 4.07 (n = 142)	−0.73 (−1.65 to 0.18)	0.12	−1.02 \pm 3.30 (n = 134)	−1.50 \pm 2.62 (n = 147)	0.47 (−0.22 to 1.17)	0.18
Skills								
Sexual self-efficacy	0.23 \pm 0.98 (n = 79)	0.34 \pm 1.17 (n = 100)	−0.11 (−0.44 to 0.21)	0.49	0.38 \pm 0.90 (n = 100)	0.41 \pm 1.01 (n = 108)	−0.03 (−0.30 to 0.23)	0.79
Sexual socialisation	−0.52 \pm 8.20 (n = 93)	0.45 \pm 7.67 (n = 147)	−0.97 (−3.02 to 1.09)	0.36	0.17 \pm 7.92 (n = 120)	−0.72 \pm 6.78 (n = 152)	0.88 (−0.87 to 2.64)	0.32
Sexual socialisation peer subscale	−0.21 \pm 5.69 (n = 101)	0.15 \pm 5.53 (n = 160)	−0.36 (−1.76 to 1.04)	0.62	0.73 \pm 5.80 (n = 135)	0.17 \pm 5.16 (n = 165)	0.56 (−0.69 to 1.80)	0.38
Sexual socialisation parent subscale	−0.28 \pm 4.11 (n = 105)	0.11 \pm 3.97 (n = 158)	−0.39 (−1.39 to 0.61)	0.44	−0.45 \pm 4.03 (n = 132)	−0.85 \pm 3.63 (n = 161)	0.40 (−0.48 to 1.29)	0.37

Outcome measure	Follow-up 1				Follow-up 2			
	Intervention, Mean \pm SD change	Control, Mean \pm SD change	Difference mean change scores (95% CI)	p-value	Intervention, Mean \pm SD change	Control, Mean \pm SD change	Difference mean change scores (95% CI)	p-value
Intentions								
Intentions	0.34 \pm 7.24 (n = 101)	0.07 \pm 7.68 (n = 153)	0.26 (-1.63 to 2.16)	0.78	1.01 \pm 7.49 (n = 122)	1.37 \pm 6.44 (n = 161)	-0.36 (-1.99 to 1.28)	0.67
Intentions self-efficacy subscale	0.50 \pm 3.14 (n = 112)	-0.05 \pm 3.25 (n = 169)	0.55 (-0.22 to 1.32)	0.16	0.83 \pm 3.39 (n = 139)	0.26 \pm 3.22 (n = 174)	0.58 (-0.16 to 1.31)	0.13
Intentions attitudes subscale	0.24 \pm 2.40 (n = 118)	-0.26 \pm 2.67 (n = 175)	0.49 (-0.11 to 1.09)	0.11	0.23 \pm 2.22 (n = 151)	0.12 \pm 2.16 (n = 181)	0.10 (-0.37 to 0.58)	0.67
Intentions norms subscale	-0.28 \pm 4.37 (n = 114)	0.31 \pm 4.65 (n = 173)	-0.59 (-1.67 to 0.48)	0.28	0.09 \pm 4.54 (n = 145)	0.94 \pm 4.06 (n = 177)	-0.85 (-1.79 to 0.10)	0.08

TABLE 36 Secondary outcomes from logic model: male

Outcome measure	Follow-up 1			Follow-up 2				
	Intervention, Mean \pm SD change	Control, Mean \pm SD change	Difference mean change scores (95% CI)	p-value	Intervention, Mean \pm SD change	Control, Mean \pm SD change	Difference mean change scores (95% CI)	p-value
Knowledge								
Knowledge	0.58 \pm 2.18 (n = 144)	0.50 \pm 2.12 (n = 175)	0.09 (−0.39 to 0.56)	0.72	0.65 \pm 2.37 (n = 167)	0.72 \pm 2.21 (n = 183)	−0.07 (−0.55 to 0.41)	0.78
Attitudes								
Comfort communicating about pregnancy	0.27 \pm 1.68 (n = 132)	0.04 \pm 1.77 (n = 162)	0.23 (−0.17 to 0.63)	0.26	0.57 \pm 1.65 (n = 162)	0.52 \pm 1.57 (n = 165)	0.05 (−0.30 to 0.40)	0.77
Comfort communicating about contraception	0.49 \pm 2.03 (n = 124)	0.15 \pm 2.29 (n = 154)	0.34 (−0.18 to 0.86)	0.19	0.87 \pm 2.27 (n = 143)	0.95 \pm 2.21 (n = 156)	−0.08 (−0.59 to 0.43)	0.75
Male role attitudes	−0.41 \pm 3.63 (n = 105)	−0.08 \pm 4.82 (n = 144)	−0.33 (−1.44 to 0.77)	0.55	−0.26 \pm 4.08 (n = 129)	−1.54 \pm 3.18 (n = 149)	1.27 (0.41 to 2.13)	0.004
Skills								
Sexual self-efficacy	0.15 \pm 1.13 (n = 94)	0.12 \pm 1.16 (n = 119)	0.03 (−0.29 to 0.34)	0.87	0.14 \pm 1.48 (n = 106)	0.14 \pm 1.32 (n = 128)	0.00 (−0.36 to 0.36)	0.99
Sexual socialisation	0.55 \pm 7.09 (n = 110)	1.27 \pm 7.31 (n = 136)	−0.72 (−2.54 to 1.11)	0.44	0.53 \pm 7.73 (n = 135)	−0.22 \pm 7.76 (n = 142)	0.75 (−1.08 to 2.58)	0.42
Sexual socialisation peer subscale	0.48 \pm 5.06 (n = 120)	0.56 \pm 5.29 (n = 148)	−0.08 (−1.33 to 1.18)	0.90	0.05 \pm 5.97 (n = 141)	0.13 \pm 6.13 (n = 152)	−0.08 (−1.47 to 1.32)	0.92
Sexual socialisation parent subscale	0.12 \pm 3.61 (n = 123)	0.55 \pm 3.53 (n = 148)	−0.43 (−1.29 to 0.43)	0.32	0.35 \pm 4.01 (n = 153)	−0.39 \pm 3.43 (n = 151)	0.74 (−0.10 to 1.58)	0.09

Outcome measure	Follow-up 1				Follow-up 2			
	Intervention, Mean \pm SD change	Control, Mean \pm SD change	Difference mean change scores (95% CI)	p-value	Intervention, Mean \pm SD change	Control, Mean \pm SD change	Difference mean change scores (95% CI)	p-value
Intentions								
Intentions	-0.01 \pm 6.68 (n = 115)	1.29 \pm 8.48 (n = 147)	-1.29 (-3.19 to 0.60)	0.18	1.22 \pm 8.32 (n = 139)	2.02 \pm 7.44 (n = 152)	-0.80 (-2.62 to 1.01)	0.38
Intentions self-efficacy subscale	0.78 \pm 3.21 (n = 127)	0.83 \pm 4.15 (n = 169)	-0.05 (-0.92 to 0.82)	0.91	1.11 \pm 3.83 (n = 157)	1.48 \pm 3.89 (n = 175)	-0.37 (-1.20 to 0.47)	0.39
Intentions attitudes subscale	-0.38 \pm 2.08 (n = 133)	-0.06 \pm 2.38 (n = 167)	-0.32 (-0.84 to 0.19)	0.22	0.08 \pm 2.27 (n = 161)	0.02 \pm 2.06 (n = 167)	0.06 (-0.41 to 0.53)	0.79
Intentions norms subscale	-0.28 \pm 4.10 (n = 135)	-0.05 \pm 4.63 (n = 166)	-0.23 (-1.24 to 0.77)	0.65	0.04 \pm 4.71 (n = 156)	0.40 \pm 4.21 (n = 166)	-0.37 (-1.34 to 0.61)	0.46

provide information on sexual health, relationships and pregnancy. Eighty-nine per cent incorrectly (as determined by the research team) interpreted particular websites (e.g. named pornography sites) as sources of such information and 10.6% correctly identified websites that do provide such information.

At baseline, when asked whose responsibility it is to prevent UTP, 75.5% of pupils who responded to Q.19 attributed a 50 : 50 ratio of responsibility to boys and to girls. Less than 1% (0.6%) of responding pupils answered that it was *only* the boy's responsibility to prevent UTP, and 0.7% answered that it was *only* the girl's responsibility. At follow-up 1, 80.7% of pupils attributed a 50 : 50 ratio of responsibility to boys and girls, with 3.8% indicating that it was *only* the boy's responsibility to prevent UTP and 0.2% that it was *only* the girl's responsibility. At follow-up 2, 83.4% of pupils attributed a 50 : 50 ratio of responsibility to boys and girls, with 0.1% of responding pupils indicating that they thought it was *only* the boy's or *only* the girl's responsibility to prevent UTP. Both the intervention and control group demonstrated an improvement towards attributing an equal 50 : 50 ratio of responsibility over time, although the improvement was more pronounced in the intervention group (13.3% vs. 10.4% in the control group).

Scores on the Male Roles Attitudes scale at follow-up 1 indicated that pupils showed a decrease in stereotypical gender attitudes to the roles of males and females in society (e.g. men work and women care). This decrease in awareness was more evident in the intervention group [-0.55 (95% CI -1.26 to 0.16)]. At follow-up 2 pupils also had a decreased awareness of gender-specific roles, but on this occasion the decrease was more evident in the control group [0.87 (95% CI 0.32 to 1.42)] than in the intervention group, although see below that there was a sustained decrease of stereotypical gender attitudes among males in the intervention group.

Increased scores on the Comfort Communicating about Pregnancy scale indicated that more pupils in the intervention group than in the control group were comfortable communicating with parents and peers about avoiding UTP at follow-up 1 [0.06 (95% CI -0.21 to 0.34)] and follow-up 2 [-0.04 (95% CI -0.28 to 0.20)]. Similarly, scores on the Comfort Communicating about Contraception scale indicated that at follow-up 1 more pupils in the intervention group were more comfortable communicating with parents and peers about the use of contraception [0.08 (95% CI -0.29 to 0.45)]. However, at follow-up 2 more pupils in the control group were more comfortable communicating with parents and peers about the use of contraception [-0.03 (95% CI -0.38 to 0.32)].

In relation to sexual self-efficacy, pupils in the intervention group scored lower than those in the control group at both follow-up 1 [-0.04 (95% CI -0.26 to 0.19)] and follow-up 2 [-0.01 (95% CI -0.24 to 0.22)]. Scores on the Sexual Socialisation scale indicated that pupils scored better in the intervention group only at follow-up 2 [0.84 (95% CI -0.43 to 2.10)], as was the case with each Sexual Socialisation subscale: peer [0.23 (95% CI -0.70 to 1.16)]; parent [0.61 (95% CI -0.001 to 1.22)].

Looking at the Intentions scale as a whole, pupils scored higher in the control group at both follow-up 1 [-0.51 (95% CI -1.85 to 0.82)] and follow-up 2 [-0.56 (95% CI -1.78 to 0.65)]. When exploring the Intentions subscales, a difference was evident. Pupils in the intervention group scored higher at both follow-up 1 and at follow-up 2 for both the Intentions Self-Efficacy subscale [follow-up 1 0.26 (95% CI -0.33 to 0.84); follow-up 2 0.11 (95% CI -0.45 to 0.67)] and the Intentions Attitudes subscale [follow-up 1 0.07 (95% CI -0.32 to 0.46); follow-up 2 0.08 (95% CI -0.25 to 0.41)], whereas pupils in the control group scored higher at both follow-up 1 [-0.42 (95% CI -1.15 to 0.31)] and follow-up 2 [-0.62 (95% CI -1.29 to 0.06)] in relation to the Intentions Norms subscale.

Differences among male and female pupils in relation to secondary outcomes were also examined. Female pupils in the intervention group scored notably higher than their male counterparts in the Knowledge scale at both follow-up 1 and 2 [follow-up 1: female 0.36 (95% CI -0.14 to 0.87), male 0.09 (95% CI -0.39 to 0.56); follow-up 2: female 0.39 (95% CI -0.08 to 0.85), male -0.07 (95% CI -0.55 to 0.41)], the Intentions scale at follow-up 1 [follow-up 1: female 0.26 (95% CI -1.63 to 2.16), male -1.29 (95% CI -3.19 to 0.60)], the Intentions Self-Efficacy subscale [follow-up 1: female 0.55 (95% CI -0.22 to 1.32), male -0.05 (95% CI

−0.92 to 0.82); follow-up 2: female 0.58 (95% CI −0.16 to 1.31), Male −0.37 (95% CI −1.20 to 0.47)] at both follow-up 1 and 2 and the Attitudes subscale [follow-up 1: female 0.49 (95% CI −0.11 to 1.09), male −0.32 (95% CI −0.84 to 0.19); follow-up 2: female 0.10 (95% CI −0.37 to 0.58), Male 0.06 (95% CI −0.41 to 0.53)] at both follow-up 1 and 2. Male pupils in the intervention group scored significantly higher on the Male Role Attitudes scale ($p = 0.004$) than male pupils in the control group at follow-up 2 and notably higher than their female counterparts in the intervention group [male 1.27 (95% CI 0.41 to 2.13), female 0.47 (95% CI −0.22 to 1.17)]. This was not evident at follow-up 1.

The total number of pupil participants who responded to the questionnaire at both baseline and follow-up 1 data collection was 666, and at both baseline and follow-up 2 data collection was 744 (see *Chapter 5*). The n values in the above table refer to the total number of participants who answered all the questionnaire items relative to the associated outcome measure at baseline, follow-up 1 and follow-up 2. Missing data can be deduced from this.

Secondary behavioural outcomes relating to the health economics evaluation model

Overall pupil responses (by treatment arm) to questions relating to secondary behavioural outcomes are detailed below in *Table 37*.

In the present feasibility study, respondents reported on having had STIs within the 6 months prior to baseline data collection, since follow-up 1 data collection, or since follow-up 2 data collection (*Table 38*). This question was poorly responded to, with 93.4% missing data at baseline, 91.3% missing data at follow-up 1 and 88.7% missing data at follow-up 2.

Reported UTPs were very low. At baseline data collection, only one respondent (5.9%) in the control arm reported having intentionally gotten a girl pregnant within 1 month prior to baseline data collection, and six (23.1%) and two (11.8%) in the intervention and control arms, respectively, reported that they did not know if they had ever gotten a girl pregnant. Only one respondent (12.5%) in the intervention group reported having been unintentionally pregnant between 10 and 12 months ago. At follow-up 1 data collection, three (12%) respondents in the control arm and one (7.1%) in the intervention arm reported having gotten a girl pregnant without intent, while one (7.1%) and three (12.0%) in the intervention and control arms, respectively, reported that they did not know if they had ever gotten a girl pregnant. One (8.3%) female respondent reported not knowing if she had ever been pregnant at follow-up 1 data

TABLE 37 Sexual frequency

	Baseline		Follow-up 1		Follow-up 2	
Overall (schools combined)	Intervention	Control	Intervention	Control	Intervention	Control
How many male partners have you had sex with in the past 6 months (or 5 months/follow-up 1, or 4 months/follow-up 2) (girls), n (%)						
One	5 (71.4)	6 (85.7)	10 (90.9)	7 (77.8)	19 (82.6)	14 (87.5)
Between 2 and 5	2 (28.4)	1 (14.3)	1 (9.1)	2 (22.2)	3 (13.0)	2 (12.5)
Between 6 and 10	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.4)	0 (0.0)
More than 10	0 (0.0)	0 (0.0)	0 (0.0)	2 (22.2)	0 (0.0)	0 (0.0)
How many female partners have you had sex with in the past 6 months (or 5 months/follow-up 1, or 4 months/follow-up 2) (boys), n (%)						
One	12 (60.0)	9 (69.2)	5 (62.5)	9 (47.4)	13 (61.9)	13 (65.0)
Between 2 and 5	6 (30.0)	2 (15.4)	1 (12.5)	6 (31.6)	7 (33.3)	5 (25.0)
Between 6 and 10	0 (0.0)	2 (15.4)	1 (12.5)	0 (0.0)	1 (4.8)	1 (5.0)
More than 10	2 (10.0)	0 (0.0)	1 (12.5)	4 (21.1)	0 (0.0)	1 (5.0)

TABLE 38 Occurrence of STIs

STI	Baseline		Follow-up 1		Follow-up 2	
	Intervention	Control	Intervention	Control	Intervention	Control
Chlamydia	1	1	2	1	1	5
Genital warts	0	2	3	0	1	4
Herpes	0	1	2	0	1	4
Gonorrhoea	0	2	2	0	1	4
Pubic lice	0	1	2	0	1	5
Trichomonas	0	1	2	0	1	4
Syphilis	0	1	2	0	1	4
HIV	0	2	2	0	1	4
Hepatitis	0	1	2	0	1	4
Pelvic infection (girls)	0	2	2	0	1	5
Vaginal thrush (girls)	0	1	2	0	1	4
Cannot remember the name	0	1	2	0	1	4
None	0	22	46	35	24	32
Other	0	0	3	0	0	0
Total STIs	1	16	28	1	12	51
Missing data (%)	93.4		91.3		88.7	
HIV, human immunodeficiency virus.						

collection. At follow-up 2 data collection, two (6.9%) respondents in the intervention group reported having gotten a girl pregnant (one intentional and one unintentional) and one respondent (4.2%) in the control group reported having gotten a girl pregnant (also unintentional), while two respondents in the intervention group (6.9%) and one in the control group (4.2%) did not know if they had. One (3.7%) female respondent reported being unintentionally pregnant at follow-up 2 data collection and one (3.7%) reported not knowing if she had ever been pregnant.

At baseline data collection seven (21.9%) respondents in the intervention arm and seven (28.0%) in the control arm reported having had sex when they did not want to within the past 6 months. These figures were seven (14.9%) and four (10.3%), respectively, at follow-up 1, and two (8.3%) and six (16.2%), respectively, at follow-up 2.

Discussion and conclusion

In the feasibility study, approximately 3% of the sample reported unprotected sex at baseline (3.6% in the intervention and 2.5% in the control group) and approximately 5% reported unprotected sex at follow-up 2 (5.4% in the intervention and 5.6% in the control group). Although not significant, there was a 50% increase in unprotected sex (as determined by the composite primary outcome, abstinence or protected sex excluding withdrawal/natural family planning method) by follow-up 2 in the intervention group (3.6% at baseline, rising to 5.4% at follow-up 2) compared with a more than doubling of unprotected sex by follow-up 2 in the control group (2.5% at baseline, rising to 5.6% at follow-up 2). Drawing from robust representative epidemiological data of school-aged children across the UK (the WHO Health Behaviour in School-aged Children Survey GB, 2014)¹²⁹ and the Young Persons' Behaviour & Attitudes Survey 2013,¹³⁰

it is known that between 25% and 33% of 15-year-olds are having sex. Looking more closely at the rates of unprotected sex for this age group, we can determine a rate of 2.8% reporting unprotected sex (overall in England, Wales, Scotland and NI) (sample, $N = 7904$ and $n = 224$ reporting unprotected sex). Therefore, the 1.3% difference (in change from baseline to follow-up 2) in unprotected sex between groups as found in the feasibility study could potentially have a significant impact on UTP rates. If such a finding were to hold true in a sufficiently powered trial, this would indicate that, for every 1000 pupils, 13 fewer would have unprotected sex during the follow-up period.

Owing to difficulties encountered in establishing a reliable and valid measure of SES (see *Chapter 4*), subgroup analysis by SES was not possible within this feasibility study as first intended. Subgroup analysis by gender was possible and revealed gender differences. In relation to the primary composite outcome there was an improvement in boys in the intervention arm but a deterioration in girls. Female pupils in the intervention arm scored notably higher in the Knowledge scale and in the Intentions Self-Efficacy and Attitudes subscales than their male counterparts. Interestingly, male pupils in the intervention group scored significantly higher than male pupils in the control group at follow-up 2 and notably higher than their female counterparts in the intervention group in the Male Role Attitudes scale. The Male Role Attitudes scale is essentially an analysis of emerging masculinities that are more gender equal versus the traditional gender-related views that men and women are unequal.

A number of additional secondary outcome measures (sexual frequency, contraceptive use and occurrence of STIs) were thought to be particularly relevant to informing a health economic evaluation. The feasibility of collecting these data was also explored. Although all three outcome measures were perceived as being feasible to collect, the occurrence of STIs was poorly responded to, with missing data in excess of 90%.

Chapter 7 Process evaluation

Introduction

The feasibility of delivering the intervention as part of an effectiveness trial was addressed by an embedded process evaluation. This allowed an examination of the school contexts, including current RSE provision, and the implementation and acceptability of the intervention among participants in the intervention group. An outline of the aims, objectives and methods employed for the qualitative component of the study is followed by an overview of findings relating to the contexts of participating schools and their current RSE provision and triangulated perceptions of the acceptability and feasibility of the intervention and research processes.

Aims and objectives

The aims of the process evaluation were to (1) assess the ways in which the intervention was implemented; (2) assess how it was received and how it could be further improved; and (3) collect details on the context of participating schools that might help to explain differences in perceptions of feasibility and acceptability.

The objectives of the qualitative component were to:

- record the current policies on, and provision of, RSE in schools and to assess what RSE was delivered in schools during the feasibility trial
- inquire into teachers' experiences of using the intervention with pupils and parents/guardians (intervention group)
- record pupils' experiences of using the intervention at school and home (intervention group)
- gain further information on implementation fidelity and teachers', pupils' and parents/guardians' reactions through researcher observation
- inquire into parents'/guardians' reactions to their children using the intervention, as well as the barriers to and facilitators of their own participation
- record participants' experiences of taking part in the trial
- obtain teachers' views on the quality of the training session offered on the intervention
- test the face validity of the quantitative instruments among pupils in the control group by conducting cognitive interviews on the topic of the questionnaire (see *Chapter 4*)
- record experiences of recruiting schools, also paying attention to refusals (see *Chapter 5*)
- record schools' reactions to being assigned to control or intervention group (see *Chapter 5* for randomisation and allocation).

Methods

A summary of the sample and data collection and analysis methods are outlined below. As illustrated in *Figure 5*, methods differed between the intervention and control groups. For interview and observation schedules, the parent's survey and pupil comment sheet, see *Appendix 3*.

Data collection

In all participating schools data collection involved individual semistructured interviews/focus group discussions and a comment sheet regarding the 'good and bad things' about participating in the trial, which was delivered to pupils immediately following the final follow-up questionnaire. In addition, in intervention schools data were collected from structured observations of at least one lesson and one parent information and discussion session in each school, and a short online parent survey.

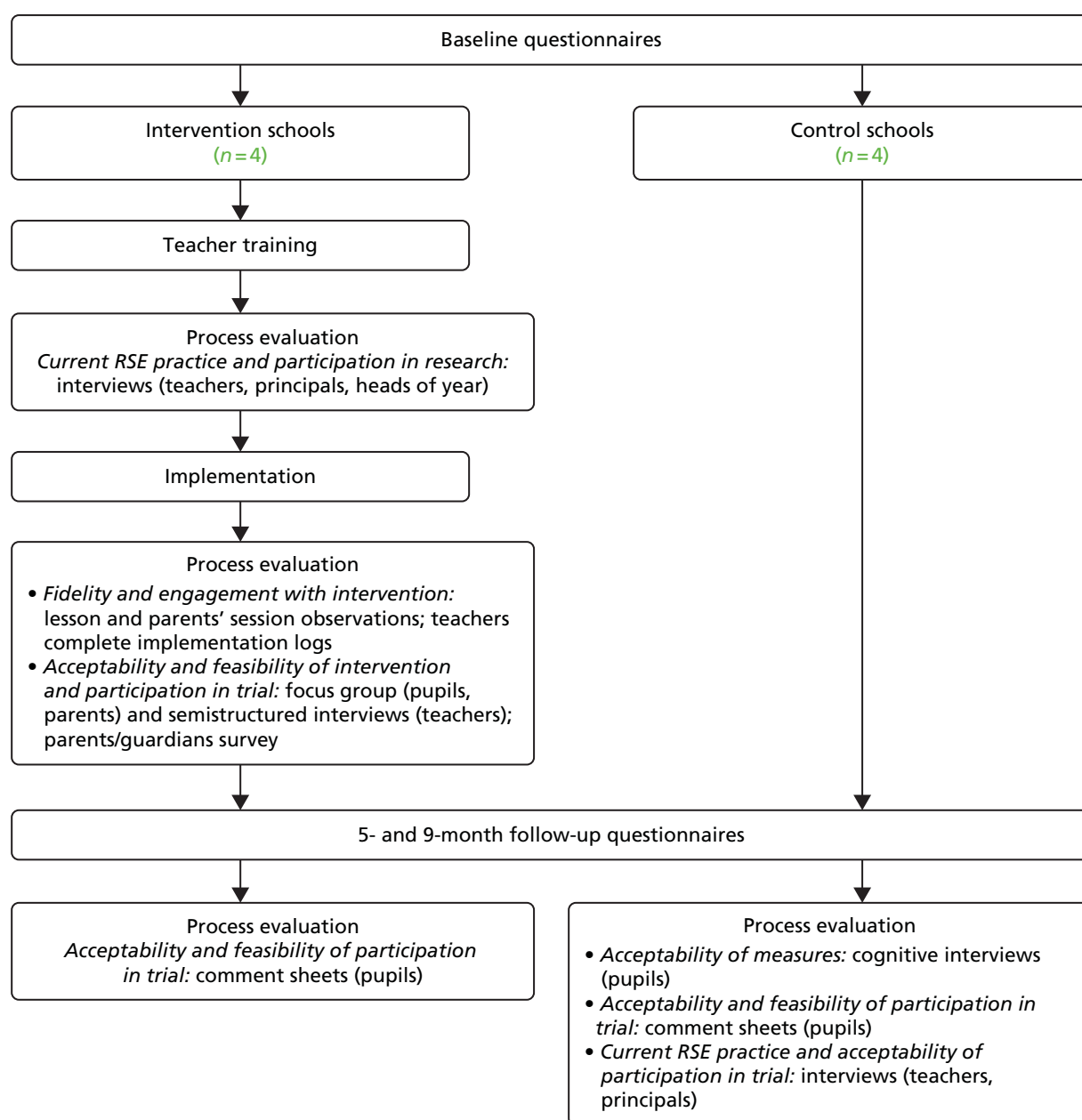


FIGURE 5 Structure and key components of the *If I Were Jack* feasibility trial process evaluation.

Intervention schools

- RSE provision: semistructured interviews with teachers (RSE-coordinators, heads of Year 11, PC VPs)
 - the nature, quantity and quality of current RSE
 - facilitators of and barriers to teaching RSE.
- Research participation: semistructured interviews with principals/heads of Year 11
 - perceptions of the conduct of research in schools in general and experiences of participation in the trial
 - barriers to and facilitators of research participation
 - engaging parents.

- Feasibility and acceptability of the intervention and implementation process and taking part in the trial: individual interviews and focus group discussions with all teachers who delivered the intervention, focus group discussions with a sample of pupils who received the intervention and a sample of parents/guardians who attended the information and discussion sessions, comment sheets provided after last follow-up and an online questionnaire sent to all parents
 - strengths and weaknesses (perceptions) of the intervention materials
 - experiences of delivering/receiving the intervention
 - experiences of the teacher training session
 - experiences of facilitating the parents/guardians' session
 - experiences of taking part in the trial
 - experiences of parent/pupil homework activity
 - suggested improvements for future trials
 - impressions of the information and discussion sessions
 - barriers to and facilitators of engaging parents in RSE

Control schools

- RSE provision and participation in the trial: semistructured interviews with teachers (RSE co-ordinators, heads of Year 11)
 - the nature, quantity and quality of current RSE
 - facilitators of and barriers to teaching RSE in school
 - experiences of taking part in the trial.
- Research participation: semistructured interviews with school principals/heads of Year 11
 - perceptions of the conduct of research in schools in general and experiences of participation in the trial
 - barriers to and facilitators of research participation
 - engaging parents.
- Feasibility and acceptability of the questionnaire and taking part in the trial: focus group cognitive interviews with a sample of pupils from two of the four schools in the control group and comment sheets provided after last follow-up
 - overall impressions of the questionnaires
 - focus on questions/words/formatting that was hard/easy to understand
 - experiences of taking part in the trial and suggested improvements for future trials.

Data analysis

Following transcription of all audio-recorded interviews and removal of any identifying characteristics of specific schools and individuals, the data were analysed using a form of thematic analysis based on the six steps proposed by Braun and Clarke.¹¹⁶ In summary, this follows well-established qualitative analysis practice of recording patterns and concepts that inductively emerged from the data and searching for data on pre-defined codes outlined in our topic guides and the literature on perceptions of RSE and UTP. These inductively and deductively derived codes were then entered in a codebook and grouped to form overarching themes. We used the qualitative software NVivo 10 to organise the data, and ensured

methodological rigour by establishing credibility, transferability, dependability and confirmability using techniques suggested by Lincoln and Guba.¹³¹ Two researchers independently coded segments of the transcripts and met to discuss and resolve any discrepancies. In schools in the control group, special attention was given to the specifics of analysing cognitive interviews. The feasibility of research methods was assessed by observation in intervention schools using structured schedules and through interviews with school staff and was subjected to the same analysis.

Findings

Sample

A total of 13 teachers across the four intervention schools delivered *If I Were Jack*. A total of 26 school personnel, 51 pupils and 10 parents took part in interviews or focus group discussions (across both the intervention and control schools).

Intervention schools

- All teachers involved in delivering the intervention ($n = 13$).
- School principals ($n = 3$), PCVPs ($n = 1$), heads of Year 11 ($n = 1$), and/or RSE co-ordinators (who did not deliver the intervention) ($n = 1$).
- A sample of pupils from each class in each of the four schools that received the intervention ($n = 39$).
- A sample of parents/guardians who attended information and discussion sessions to take part in focus group discussions ($n = 10$).

Control schools

- Teachers designated as trial champions in each school ($n = 4$).
- Heads of Year 11 ($n = 1$) and school principals ($n = 2$).
- A sample of pupils from each class who took part in cognitive interviews in two of the four control schools ($n = 12$).

Data were also collected from structured observation of five lessons delivering the intervention and from 29 parents who responded to the online survey.

An overview of the context of participating schools, including a brief description of each school, is followed by an outline of existing RSE provision. The remainder of the section discusses results relating to the acceptability of the intervention and the feasibility of implementation and participation in the research.

The context of participating schools

As indicated in *Table 39*, of the eight schools that took part in the study, seven were located in urban areas and one in a rural area; five were secondary schools and three were grammar schools, with the former enrolling pupils regardless of academic ability and the latter accepting pupils with the highest marks in entrance exams. In terms of management type, three were controlled schools (i.e. managed by the Education Authority), two were RC maintained schools, two were voluntary (i.e. managed by a board of trustees) and one was grant maintained. Three schools were in affluent areas, with the percentage of pupils eligible for free school meals ranging from 4% to 15%, and five were in deprived areas, with the percentage of pupils eligible for free school meals ranging from 32% to 48%.

Relationships and sexuality education in participating schools

Three overarching themes emerged relating to the provision of RSE: (1) existing provision – content, frequency, co-ordination and delivery; (2) attitudes towards RSE; and (3) obstacles to and facilitators of quality RSE. In general, it emerged that provision was extremely variable across the eight schools and, in most cases, not seen as a priority subject, although those staff members tasked with co-ordinating RSE

TABLE 39 Overview of participating schools

School ID	Location	All pupils 2014/15	Year 11 pupils 2014/15	School type	Management type	All pupils eligible free school meals (%)	% religion per school	All pupils with SEN per school	Trial allocation
10	Urban	667	141	Secondary	Controlled integrated	32.4	P: 74.4 C: 5.9 O: 19.8	213	Control
11	Rural	610	98	Secondary	Catholic maintained	48	P ^a C ^a O ^a	113	Control
12	Urban	815	122	Grammar	Controlled	15	P: 62.7 C: 6.5 O: 30.5	82	Control
13	Urban	617	124	Secondary	Grant maintained integrated	57.4	P: 50.4 C: 31.3 O: 18.3	268	Intervention
14	Urban	478	93	Secondary	Controlled	35.1	P ^a C ^a O: 16.5	113	Intervention
15	Urban	882	153	Secondary	Catholic maintained	45.5	P ^a C ^a O: 0.0	235	Intervention
16	Urban	1080	155	Grammar	Voluntary Catholic	8.5	P: 0.0 C: 99.5 O ^a	33	Control
17	Urban	1077	158	Grammar	Voluntary other managed	4	P: 62.7 C: 12.4 O: 25.0	53	Intervention

C, Catholic; O, Other; P, Protestant; SEN, Special Educational Needs.
^a Figure suppressed under rules of disclosure.

were all motivated to prompt changes in this regard. In some schools there was a clear sense of a considered, planned, well-structured RSE programme, while in others, provision was so haphazard that even the RSE team had difficulties articulating the content and frequency of provision. In most of the schools pupils remembered learning about reproduction in Biology but could recount few, if any, other instances in which teenage pregnancy was mentioned.

Theme 1: existing provision – content, frequency, co-ordination and delivery of Relationship and Sexuality Education

Representatives of all eight schools indicated that pupils were provided with some form of RSE. All reported having a written RSE policy. One school had published their policy on their website, three provided unpublished copies for analysis and three indicated that their policy was under redevelopment. The documents contained information on the school ethos, the morals, values and principles underpinning the policy, a general list of topics covered within the RSE programme and information on curriculum provision and delivery.

All eight schools provided most of their provision within the PD strand of the LLW curriculum (see *Appendix 7*), although subjects such as reproduction, relationships and sexuality were also reported to be covered in subjects such as Science, RE and Home Economics and also touched on in PC/form classes. In one school pupils received eight additional RSE lessons per year as part of their PC classes. All used the 'Insync' PD Programme developed by the CCEA (see *Appendix 7*) at Key Stage 3 (Years 8–10) but provision at Key Stage 4 (Years 11–13), for which there are no official curriculum materials, was highly variable (see *Appendix 10*).

Although most of the school representatives had received some training, either during their initial teacher training or by attending short courses and conferences post qualification, they agreed that the majority of those delivering the RSE content would not have received any training specific to the delivery of RSE. Some schools had planned external training for the near future, whereas others provided in-house training when possible.

Teachers in the RC schools described their general approach as one that focused on right information, right choices, loving relationships and always being in line with the RC Church's teachings and ethos.

Our [current RSE] policy very much was based on the ACCORD [a voluntary organisation operating in NI that aims to promote a deeper understanding of Christian marriage, and to offer couples the means to safeguard and nourish their marriage and family relationships]. It's supposed to cover sexuality, morality, ethics, values, personal . . . there's a few general things there, where obviously throughout our whole curriculum are mentioned, status of family, sacredness of life, obviously confidential child protection issues, homosexuality . . . We are all for abstinence until you are within a healthy relationship.

When asked about how pupils are taught about birth control in biology and RE, teachers responded:

It's really trying to avoid teenage pregnancies as well, pointing out to them, you know, that they know the risks, so that they're not naive and silly and end up having a baby because they had no information. It's all about making sure that they know the risks of pregnancy and when they're older, knowing how to avoid it.

For content, frequency and delivery of RSE in participating schools, see *Appendix 10*. The information is based on self-report and the limitations of that are recognised. Teachers were vague as RSE content varies so much and many schools do not have a structured programme.

Theme 2: attitudes towards Relationship and Sexuality Education

In three schools, representatives gave the impression that, in general, RSE remained a sensitive, if not controversial, subject and that attitudes towards RSE among school staff were mostly negative, with many staff feeling uncomfortable, with some emphasis placed on the particular difficulties in engaging with the issue of homosexuality.

In both RC schools, teachers gave the impression that PC in general, and RSE in particular, were an important priority and generally accompanied by positive attitudes, and that academic focus did not take precedent.

In the controlled grammar school the Head of Year suggested that PC was seen as important, conceding, however, that RSE may not always be prioritised.

Teachers thought that pupils enjoyed the RSE provision but probably wanted more.

In all of the schools it was felt that attitudes towards RSE in the school were changing and most were anticipating further changes following new guidance on the provision of RSE from the Department of Education in 2015 (see *Appendix 7*).

When asked for their views on the quality of RSE provision in the school, most teachers were positive, but also agreed that it varied from teacher to teacher, with most agreeing that further improvements could be made.

I suppose what we're doing is fairly good, I must admit. I think it's very high quality but, like that, I think it does need to be evaluated, reviewed and made better, as we would do with any subject.

Theme 3: barriers to and facilitators of quality Relationship and Sexuality Education

Commonly mentioned barriers included negative attitudes and lack of motivation on the part of team members, a lack of time or priority afforded to RSE provision, an unavailability of up-to-date resources, financial constraints, discomfort among teachers and a lack of opportunities for training.

Facilitators included a strong, experienced team, supportive management and available resources. In some schools quality of provision was attributed to dedicated, experienced team members and a well-planned programme with a sound underpinning ethos.

In one school, the LLW teacher felt that an academic focus and conservative, perhaps naive, attitudes among staff members were detrimental to the provision of RSE.

It's OK. It could be a lot better, and I think . . . there are elements of the natural conservatism, the elements of the focus being on academics because we're the school that we are, versus the misconception that, because the kids are from the backgrounds they're from and they're at the school they're at, they're not getting up to this nonsense, as opposed to accepting that they are getting up to this nonsense.

Most schools mentioned having used an external organisation such as 'Love for Life' (Love for Life, Waringstown, UK). Some no longer used the service owing to financial constraints or decisions to manage their own RSE locally. A number of staff felt that RSE provision by external facilitators (as an adjunct to that provided in-house) has advantages for both staff and pupils.

Acceptability of the intervention

Although some pupils felt that the whole idea of RSE was embarrassing and awkward in relation to teachers and fellow classmates in general, when asked about their impressions of the intervention overall, most young people and teachers in intervention schools were positive and provided suggestions that they felt would help improve the various components.

Acceptability of the intervention

Two themes relating to the acceptability of the intervention emerged from pupil focus groups. These related to (1) the strengths and limitations of the core intervention and (2) personal lessons learned. The first theme concerned pupils' views on the good and bad elements of the IVD and related activities, as well as suggestions about elements of the intervention that they felt should be changed. The second theme related to perceptions of actual or potential personal gain or loss as a result of using the intervention. Three themes relating to the acceptability of the intervention emerged from teacher interviews and focus groups. These themes related to the strengths and limitations of (1) the core intervention, (2) the teacher training session, and (3) the parents' information and discussion session.

Strengths and limitations of the core intervention (film and accompanying activities)

Teachers agreed that pupils enjoyed and easily engaged with the IVD and, although there were variations across class groups, pupils interacted well with most of the accompanying activities. All participants agreed that the overall concept of the intervention was acceptable and, allowing for minor changes to some of the activities, most said that they would use it again.

Positive aspects included the fact that it was locally set, realistic, relatable, interesting, informative and helpful.

I think, as resources go, it's one of the best I've seen out there because anything we have is quite ancient, dated or from, like . . . England, Australia . . . We're very lucky to have a resource that is very current and set, you know, in the local area.

I think it's actually a very good resource, and I think the fact that it's coming from a boy's point of view is unique and the pupils took to that well, you know, because they're always hearing about teenage pregnancy always more geared from the girl's point of view. So, I think they found that maybe kind of . . . made them more interested in it, just from the very start.

The most common complaint about the IVD from pupils, which was supported by some teachers, was that there were too many questions embedded within it, too many stop-starts and that some of the questions seemed repetitive or did not include the specific option that the pupil wanted to pick.

It would have been nice to have the whole film and then to go back to run through it, without the questions, because the questions, you were kind of . . . it took a long while just to get through them.

Some pupils thought that the film was outdated, a bit 'cheesy' and the behaviour of the actors within a bit 'childish' and in need of updating, whereas others said that updating the film was not necessary because, when they compared it with other resources they used in school, it seemed very contemporary. Some pupils attributed the outdated feel to the assumption that young people had not been involved in writing the script.

Although participants did not spontaneously mention the focus on the male protagonist's perspective as a limitation, when prompted, all agreed that more focus on the female protagonist's perspective would perhaps be helpful. One suggestion was that an activity focused on the girl's perspective might be beneficial. Male and female participants also agreed, however, that the focus on the boy's perspective was both acceptable and relevant to them.

It would be better if you could, like, go from, like, each side, each perspective, if they took, like, the girl and the boy. It would be better because you'd get a rounded perspective of what it would be like.

Some pupils were disappointed by the fact that the story did not have an ending and saw this as one of the biggest weaknesses of the film. Teachers reaffirmed this feeling among pupils.

The only thing that really annoyed me about it is they don't actually tell you what she does with the baby at the end. Like everybody wanted to know!

Most teachers agreed that providing pupils with a worksheet to complete the 'Pause: Fast Forward: Rewind' activity worked best. Pupils agreed that they would prefer less written and more interactive or discussion activities, although some did say that they enjoyed the opportunity afforded them by the worksheets to think things out in private before discussion.

Regarding homework, the majority said that homework was a bad idea, mainly because they did not usually have homework for LLW, PC or RE, and teachers confirmed that homework was not a good idea

because pupils resisted this as a result of not being accustomed to having homework in this context. Although some pupils said that they did the homework without difficulty, most said that they did not do it at all or that their teacher asked them to do it during the class period. Pupils from the grammar school weighed up the time involved in completing homework against other priorities.

Four of the 10 additional activities sparked particular conversation: (1) 'If I had a baby'; (2) 'Making a difficult decision'; (3) role-plays; and (4) the parents' survey. There was general agreement that the 'If I had a baby' activity, which asks young people to compare their own schedule with that of a parent with a 6-month-old child, was enjoyable and for some even shocking.

Yeah. That was . . . that was probably one of the most effective because it was a real eye-opener. It was something that they talked about even after we'd done it, even the following week – 'I couldn't believe that . . .' So, em, something like that, where there's a comparison of their own life, I think really works.

In relation to the 'Making a difficult decision' activity, which asks young people to consider the pros and cons of keeping the baby, having the baby adopted or having an abortion for Jack, Emma and the baby, teachers noted, and many young people fed back, that they found the exercise difficult, particularly when trying to think of the pros of abortion for the baby.

I think they were embarrassed to say because this was like is there any pros for the baby with, for example, abortion. For some of them, they found it quite . . . well, they would say, 'But how could there be a pro if they're dead?' and for them to say that out loud, some of them struggled to put that into words . . . It was as if we were nearly tricking them – 'Is there a positive?!'

The role-play activity sparked a mixed reaction, with some young people saying that they loved it and others saying that it was 'embarrassing' and an opportunity for members of the class to ridicule those who 'went to the top of the room' to act out the parts. Although some teachers were adamant that their pupils would not engage in role-play, others felt that it was worth keeping in because some pupils enjoyed it and through watching others, those who will not participate can still benefit.

Finally, although some pupils appreciated the potential benefit, the parents' survey was associated with predominantly negative views. The activity asked pupils to interview a parent/guardian (or other trusted adult) regarding their views of the *If I Were Jack* film. Although some young people said that they had never received the worksheet, others said that they consciously did not do it or 'forgot', with only a few girls admitting that they had completed it with their mother and one boy saying that he had done it with his older brother. The majority mentioned embarrassment and fear of awkwardness as primary reasons for avoiding the activity. In addition, many anticipated that bringing up such a subject had the potential to encourage further discussion from parents – the thought of which put off most pupils. For some pupils, the concern was less about embarrassment and more about their parents' actual or perceived unwillingness to engage with them. Some pupils thought that it would better to do the activity with friends or a sibling.

I'm like close to my parents – I can tell them anything, but I wouldn't do it. Like I don't know . . . it's weird. It's weird talking to your parents, you know, especially when you're like 15. Like sitting down and just be like, 'Yeah, by the way, I learned about sex today'.

I got it, but my Mum said that she couldn't fill it in because she would be hypocritical because she got pregnant at 17.

Teachers reported mixed views on the parent survey homework exercise, with many reporting that the majority of pupils chose to leave the material for the exercise behind and not even consider taking it home to discuss with parents. When asked if the teachers got a sense that this was the first time the pupils had discussed such matters, responses included:

Yes . . . One of the kids was like, 'My dad was like really proud of me for going to him to tell him that this had happened! 'And it was just like . . . because that had led into a conversation where his dad had said to him, 'If this did happen to you, would you feel that you could come and ask me for advice and help?' and he said, 'Well, on the basis of this response, yes,' and his dad was going, 'Good, I'm really pleased – this is fantastic, because this is what I'm here for! OK, I'd kill you, but [laughing] . . . I would be angry at you, but it's really good that you would come and speak to me about that'. So, there was a bit of sort of the kids going . . .'. My dad's actually reasonable . . .' do you know [laughing]?! There was some things like that, where they have this idea that their parents are terrifying, and actually, they just care, you know.

Regarding the controversial statements activity, teachers reported that most students enjoyed it:

Yeah, and then they got a little bit of feedback. But I just wandered around, without being too intrusive, letting them . . . It was interesting what they picked up on, what they chose, what was important . . . They got a laugh with some of them as well, you know, like 'Should women shave their legs' . . . I mean, they were really talking about it, instead of just sitting hoping that I wouldn't come round. I was listening and they really were discussing, so that was good.

One teacher, however, did not do the controversial statements activity, as she felt that it would not work with her class group and was unrelated to the rest of the activities.

Teachers agreed the intervention could have been broader in scope.

I do think there could have been much more discussion on other things, you know, like if you do sleep around, there's other things can happen, like STIs and all of that, and I really felt that was missing in it. I mean, I know you're just talking about the consequences, but they've slept together, do you know, and they're . . . so I just felt that we could have taken it a wee bit further in that regard.

Participants offered suggestions for minor changes to the intervention (see Appendix 11).

Personal lessons learned

The most commonly mentioned personal gain was that the intervention offered pupils more insight into the possible consequences of an UTP on their lives.

And realising you probably wouldn't have a . . . like a career . . . Well, you would, like you'd probably get like a job that you wouldn't really need much qualifications, but if you had a baby, you'd probably be less likely to go to university when you had to take care of a child.

For some, the intervention seemed to challenge existing beliefs, such as the following.

- Babies are not hard work:

But people are always saying babies are worth it, they're genuinely worth getting up at, you know, 4am.

- Abortion is an option for some people:

I understand that it has to be put in because it is an option, but I do like think it's really stupid, especially since it's like allowed up to like 24 weeks or something I think it is, which that is technically murder because like it's breathing, which is . . . But the boys were being really immature about that question, like saying stupid things like 'Yeah, do that now', and it annoyed like quite a lot of us.

- Men have feelings and responsibilities when it comes to UTP:

Yeah, it was good to see how . . . because, usually, you focus on the girl, like how it would affect the girl, but there, you see . . . it isn't affecting the guy physically at all, but it's . . . like the moral implications of it, so how he'd think . . . what would be right, and usually you don't think of that. Usually, guys are portrayed as just leaving.

In addition, some participants mentioned that there were advantages to putting yourself in Jack's shoes and that the intervention had prompted them to consider teenage males' roles and responsibilities.

I'd never thought about it that way, like from a guy's point of view. It was all from a girl's point of view, like going through that.

Strengths and weaknesses of the teacher training session

Although process evaluation findings indicated that teachers felt that they could implement the intervention with the help of the detailed 'teacher's information booklets' and an online video, they were adamant that the training session was useful for them and suggested that, for the purposes of a future trial, the face-to-face training session should be retained.

Strengths and weaknesses of the parents/guardians' information and discussion session

As noted in *Chapter 5*, recruitment of parents and guardians to attend the school-facilitated information and discussion session, to view the information session video on the YouTube channel and to respond to the parent's online survey was extremely low. Twenty-nine parents/guardians responded to the online survey, with 22 indicating why they had not attended the information and discussion session (*Table 40*).

One mother wrote that her son had asked her not to attend:

My son was a little embarrassed by the subject matter being shown and discussed and requested that I did not attend.

TABLE 40 Parents'/guardians' reasons for not participating in the information session

Reason for not attending	n (%)
I was unable to attend owing to other commitments	15 (68)
It was not at a suitable time of day	4 (18)
I did not know about it	2 (9)
I did not need information on how to talk to my child about avoiding teenage pregnancy	1 (5)
I thought it might embarrassing	1 (5)
It did not interest me	1 (5)

Mothers and teachers attending focus group discussions shared speculations about why parents may not have attended and why the general experience of the teachers was that parents were difficult to engage in non-curricular activities in general. Reasons included that they were generally disinterested or apathetic, or that they did not feel the need to talk about such issues because they have already addressed them with their child or that they did not have time to attend owing to work commitments (as a result of the early timing of the event), or an unwillingness to give up other commitments, the distance from school and language barriers.

One teacher in the intervention group spoke of previous successes using short animations relating to online safety. Other teachers agreed that sending a link to a video via text message might reach more parents. Some teachers suggested alternative ways of engaging parents, including tagging on the session to other events that are more likely to be attended, such as parents' evenings (when parents meet with their children's teachers regarding progress).

Feasibility of implementation

Experiences of implementation

Three themes emerged relating to pupils' experiences of implementation: (1) characteristics of the ideal implementer; (2) facilitators of and barriers to successful implementation; and (3) indications of fidelity.

Characteristics of the ideal implementer

Most pupils were happy with the fact that their teacher had delivered the intervention; however, when prompted they agreed that there were certain personal characteristics that made some teachers more suitable than others to deliver sexual health-related subjects. Commonly mentioned characteristics were a sense of humour, light-hearted, not too serious, someone who pupils respected, who was open and easy to talk to and who was encouraging. Many pupils thought that there was a general advantage of younger teachers, referring to them as being more relatable. Other interesting feedback included a desire for teachers not to react to what they were hearing and that it was thought that male pupils were more receptive to male implementers. One pupil expressed concern that your teacher might remember what you had said and make assumptions about you in future years to come. Pupils also differed according to whether or not they thought that the intervention should be delivered by someone internal or external.

Somebody that you didn't know, it would be far easier to talk to them about it.

I think it's better with one of your teachers because like you're better talking to them because they understand you more, and I think you can trust them and open up to them better, where if it had have been just some random person comes in, I think you'd be more like 'Should I tell them or should I not? Will you trust them or will you not?' Like you feel uncomfortable . . .

One teacher implied that her ability to address embarrassment from the outset had facilitated implementation and engagement. One teacher also related how the fact that she had known the pupils for such a long time helped to alleviate any awkwardness.

Facilitators of and barriers to successful implementation

Most teachers noted the value of an 'off the shelf' resource that required little preparation, with the exception of reading for familiarisation and photocopying the materials needed. However, two teachers in one school thought that there was too much preparation involved, mainly because they felt that some of the activities were too repetitious or not appropriate for their particular students and needed to be supplemented with others that they sourced themselves. In general, teachers expressed a need to have flexibility in how they chose to use the resource, in a way that they felt would work best for their class group.

Although all four intervention schools attempted to watch the online film on individual computers with at least one class group, owing to technical difficulties relating to the school network, all but one school

proceeded to show the film on an overhead projector. Although teachers saw the advantages of using individual computers, most agreed that showing the film on an overhead was less hassle and also had benefits for pupils with reading difficulties.

I think, when we were able to do it with the overhead, you could have a bigger control of the pace, so that one child hadn't got nearly everything finished in one lesson, and you could add in wee bits where you felt . . . or it also allowed you to explore, if somebody said something totally off-the-wall, that you could stop and say 'Let's explore that – let's think about it a wee bit more'.

Some pupils could see the advantages of using individual computers ('Filling it in yourself, you do it at your own pace and it goes into your head better'), whereas others commented that the fact that the teacher could read and explain the text in the questions as an advantage ('Everyone had different opinions for the answers . . . And like you could hear what everybody's different opinions were, which is good.').

A common problem was that there was not sufficient time, particularly for watching the film in schools with a 35-minute lesson. One teacher suggested that it would be better to show a section of film over three lessons and follow this with an activity. There was a mixed reaction from pupils to this suggestion, however:

It's an easier flow, easier to understand, if it's all in one go.

I just think it's easier to understand because then, if you're doing a bit at the time, it's easier to kind of process and then you can think about the questions more, instead of just taking in the whole video. I think it's just better, just easier to understand bit by bit . . .

One pupil felt that the whole intervention would have been best delivered all in one go over 1 day.

Teachers agreed that the intervention was targeted at the correct age group, but many felt that it could also be used with a younger year group, with most suggesting Year 10.

Some pupils and teachers reflected on the distraction caused by peers who did not take it seriously or were too 'immature' to contribute seriously to discussions. This was notably attributed to boys.

Pupils noted the importance of confidentiality, concerns that something said would end up on Facebook (Facebook, Inc., Menlo Park, CA, USA) the next day and were uncomfortable with the notion that teachers and fellow pupils may be trying to look at their answers.

Others reported that the intervention worked less well for more challenging class groups.

Fidelity of implementation of the protocol

As detailed above, teachers often felt the need to adapt the resource to their own class situation, or were logistically forced to adapt in the moment. In one school both teachers decided not to deliver lesson four. Although both teachers agreed that they felt the pupils had had enough of the intervention after three lessons, one conceded that a lack of time was also a factor. Some teachers noted that they took longer than expected to deliver the intervention and that some pupils missed out on some activities owing to interruptions such as closures as a result of heavy snow, bus strikes, fire drills and pupils being taken out of class for sports and music activities. Some teachers extended the lessons in order to ensure that the homework activities were completed within school time. One teacher decided to focus on one dilemma rather than the four provided in the pack. Some teachers felt that allowing small group discussion prior to whole group discussion worked best for their pupils.

One pupil suggested that his teacher had not implemented the intervention as instructed, suggesting that the pupils were sat down in front of the IVD without explanation, provided with the worksheets and left to their own devices to figure out what to do.

Most of the teachers said that they delivered all activities, even if they had to extend the number of periods in order to do so. In one school, however, the teachers decided to leave out various activities, including the scavenger hunt, the parental survey, the controversial statements activity and activities involving role-play.

Fieldworker reflections on data collecting in schools

The fieldworkers reported that the majority of data collection was carried out in accordance with protocol and that most schools and children were accommodating and happy to participate. When asked about any problems they encountered, three overarching themes emerged from their reflections. These were school environment, pupil issues and researcher issues. First, in relation to school environment, fieldworkers initially experienced difficulties with computers and online questionnaires and reverted to paper questionnaires. In addition, pupil proximity in classrooms during questionnaire completion was thought by some to be too close and to potentially compromise confidentiality. Although teachers were thought of as helpful during the initial stages, some thought that their continued presence in the classroom may have affected the children's confidence to ask questions and seek help. In one school, examinations ran over time, which resulted in timing issues, and buses arrived to take children home before they could complete the questionnaire. Second, in relation to pupil issues, fieldworkers noted that a few were confused about the confidentiality of the study, some had difficulty describing their family circumstances within the questionnaire, and some struggled with the wording of questions and terms used. Third, in relation to researcher issues, a few fieldworkers commented on dealing with challenging behaviour in the classroom and the extra time required to clarify the process, define terms and provide additional support for individual pupils (see *Appendix 13* for categorised raw data and themes).

Feasibility of participation in the trial

Pupil comment/feedback sheets

When the intervention was complete, pupils were asked for their views about their participation in the trial. They were asked to write down their thoughts on the 'good things' and 'bad things' about taking part via a student comment/feedback sheet (see *Appendix 11*). A content analysis was completed on some of the pupil responses; see *Table 41* for details of the sample.

Summarising the data

Absolute frequencies were used as a means to summarise the data (i.e. the number of times a statement or issue was found in the sample). The young people's comments in relation to the 'good things' about taking part in the *If I Were Jack* trial focused on eight categories, whereas the 'bad things' about taking

TABLE 41 Number of respondents

School number	Total number of responses
10	43
11	73
12	47
14	39
15	21
16	85
17	94
Total: 7 schools	Total: 402 pupils

part focused on nine categories of data (see *Appendix 13*). These are presented hierarchically and suggest that, although the majority found taking part informative, interesting and/or relevant, which made them think more about the issues addressed, they thought that the questionnaire was too long and repetitive and therefore boring to complete. Most thought that missing formal class time and receiving sweets for their participation was good and those who thought missing class was a 'bad thing' focused on sport and games as opposed to missing out on more traditional subjects. In general, the questionnaire was considered easy to understand and to complete by most; however, there were a few who experienced confusion around the use of some terms and the question structure. In relation to the content of the questions, a lot of the young people thought that they were very personal, which made some feel uncomfortable. However, others felt comfortable with this and enjoyed the opportunity to share their views. Only two thought it awkward when parents became involved. For a lot of the young people some questions did not apply and confidentiality was questioned in terms of pupil proximity and completion time of the questionnaire. It was felt that those who were sexually active were easily spotted as they took longer to complete the questionnaire; likewise, those who were not sexually active required less time. Members of the research team who collected data in the schools were thought of as helpful and nice, and four young people commented that they were happy to help with research in general. The puzzles at the end were liked, although a few thought a prize should be awarded for completion of these.

Is there anything that you think we should change the next time we do research like this?

The young people were also asked to highlight areas for improvement. Fifty-one young people in the sample expressed their views and provided guidance on the way forward for this type of research (see *Appendix 13*). Some common issues emerged from their comments, which were themed accordingly. This resulted in four themes that described the young people's views and suggestions in relation to (1) the relevance of the questions to their personal experiences; (2) the practicalities of completing the questionnaire; (3) issues around the 'youth-friendliness' of the questionnaire; and (4) the restrictive nature of the closed question format and how they would like an opportunity to better demonstrate their knowledge, morals and subjective opinions on the issues. Each theme is detailed below with a cluster of excerpts from the young people's responses, which illustrate the essence of the theme.

1. Relevance

- i. questions relate too much to a female aspect of a relationship/sexual encounter
- ii. make one just for boys and a different one for girls
- iii. have a greater range of questions, in particular for those who do not plan on having sexual relations until they are older
- iv. change the wording on questions, as they made me feel like I should have had these experiences before
- v. put the option 'hasn't happened' in some questions.

2. Practicalities

- i. I would not like to do anything else about things like that because I do not like sharing my details with other people
- ii. put people further away from each other; make it more confidential
- iii. explain it more each time
- iv. spread out the tests more
- v. make the questionnaire shorter
- vi. do not be as forward with the questions
- vii. I would not ask personal details such as postcode.

3. Youth-friendly

- i. make it less formal, include some funny images or funny stories to make the person completing the questionnaire more comfortable and at ease
- ii. make it sound less complicated
- iii. change some questions so they are not as personal or about other people that you may know
- iv. rethink how questions are asked; some questions are hard to understand
- v. word things better.

4. Subjective opinions

- i. ask what the school says on pregnancy and how the school teaches students to avoid it
- ii. maybe educate us more on the outcomes of UTP so we have a better understanding
- iii. ask what your opinion of teenage pregnancy is and what are others' opinions (e.g. peers, parents).
What is your opinion of people who are sexually active at a young age?
- iv. have fewer multiple-choice questions so people can give their own opinion.

Teachers

Teachers were asked about their experiences of taking part in the research. One teacher in a comparison school was disappointed not to receive the resource. The designated trial champion in one school spoke about the interruptions to her own work owing to technology problems experienced by those delivering the intervention and the importance of support from the research team. In another (grammar) school in the control group, the trial champion indicated that, although it had been challenging to begin with, he had learned to deal with the organisation of data collection over the course of the year and had really valued help received from classroom assistants.

Several teachers felt that offering pupils the opportunity to opt out was not in line with their usual way of doing things and led to disruption.

I know that we had a significant number of pupils who were given the opt-out option. Ehh I'm not sure if I would give them that option. I can probably understand the reasons behind it but, ehh, that option to opt-out is easy and some of those pupils who opted out are the very pupils who you would want to get a response from.

Some teachers noted that pupils found it hard to understand the connection between the questionnaire and the resource.

The baseline questionnaire, I think [was confusing] for some pupils, because then, whenever . . . whenever they went to then do the resource, they felt, well, what had that got to do with . . . where was the connection? They didn't see that there was a connection in there.

One principal felt that it would have been more convenient to allow pupils to complete the questionnaires online at a time that suited them. Teachers also noted the fact that those pupils who took part in the focus groups enjoyed 'having their say'. The principal of one of the schools in the control group reflected on the inconvenience of taking part in two research studies at the same time but also noted that the *If I Were Jack* trial was well organised.

Discussion and conclusions

This feasibility trial implemented an embedded process evaluation. Existing provision (content, frequency, co-ordination and delivery) was assessed. In NI there is no official curriculum material targeted to Key Stage 4 (Years 11–13). Year 11s were the participating year group in this feasibility study, although there

was a consensus among participating teachers that they would also like to use the intervention with Year 10. In general, it emerged that provision was extremely variable and not perceived as a priority subject. Some schools had well-structured RSE programmes, whereas others had difficulty articulating the RSE provision within the school. Pupils recalled little to no attention or emphasis placed on UTP.

Although RC schools described their approach as always in line with the RC Church's teachings and ethos, this did not appear to alter the nature or attitude towards RSE provision compared with non-RC participating schools. Participating grammar schools, although academically focused, were not distinguishable in terms of their existing RSE provision. Teachers reported a general sense that RSE provision remained somewhat sensitive, controversial and that attitudes towards RSE were highly variable, with some reports of religious conservatism and homophobia, and that improvements could be made. Training and opportunities for training appeared to be all but absent since teachers had qualified.

Regarding the general acceptability of the intervention and participation in the trial, *If I Were Jack* was positively received, with pupils enjoying and engaging particularly well with the IVD, as well as with most of the accompanying materials. Most teachers reported a willingness to use the intervention again, and pupils and teachers were forthcoming in suggesting minor changes for improvement. Pupils and teachers were particularly enthusiastic about the local context of the IVD and the uniqueness of the fact that it was pitched from the teenage male perspective. Both male and female pupils felt that more focus on the girl's perspective would be helpful. In a full trial we would consider incorporating more 'If I Were Emma' questions into the IVD and adding additional focus on girl's perspective in accompanying activities. One school expressed disappointment not to have been allocated to the intervention arm.

There was a consensus that the homework component was not well received among both pupils and teachers due, in part, to an embedded tradition of RSE not being associated with homework, but, most notably, to pupils reporting parent's actual or perceived unwillingness to engage with them. The 'If I had a baby' activity was very well received, with teachers reporting that pupils were still engaging with the context of the activity weeks later, attributing the fact that pupils could really compare to their own current lifestyle as the main trigger for conversation.

One notable area of negative feedback was with respect to the 'Making a difficult decision' activity, where one question asked pupils to consider the pros and cons of having the baby, having the baby adopted or having an abortion for Jack, Emma and the baby. The concept of considering pros for the baby in relation to abortion was not well received. As is often the case, engagement with role play was highly variable.

Teachers reported that should *If I Were Jack* become openly available, an online training video for teachers would suffice but they acknowledged the need for a researcher-led teacher training session in the context of a research trial so that issues such as fidelity and timing of the intervention could be adequately explained and reinforced. Moreover, our own observations of the variability of implementation encountered during the trial highlighted the absolute importance of appropriate training around issues such as those raised by the teacher. In a full trial we would, therefore, retain the face-to-face training session and we would also aim to reinforce the importance of relaxed and confident delivery and build confidence by allowing teachers the opportunity to consider the intervention in group settings with a longer training session being implicated.

Engagement with parents was particularly difficult during this feasibility study. The embedded process evaluation offered some insight into why this may have been the case. The most significant thing to emerge was that getting parents to attend a session dedicated to explaining the intervention was likely to be unobtainable for a variety of reasons, mainly because it was impossible to host such a session at a time that would be commonly accessible to all target parents.

Regarding the feasibility of implementation, pupils were generally responsive to the fact that teachers were the ones delivering the intervention. Pupils did emphasise that certain personal characteristics attributed to

individual teachers stood out, such as having a sense of humour and being easy to talk to, in addition to younger teachers being more relatable.

In relation to facilitators of and barriers to successful implementation, teachers valued an 'off the shelf' resource, which required little preparation to deliver it. It was anticipated that ensuring 100% compliance in relation to fidelity of implementation to protocol would be almost impossible in relation to teachers. The process evaluation confirmed this to be the case. Teachers did report adaptations to the delivery of the intervention, often to meet the needs of their own particular class, or owing to logistical constraints. Field worker reflections confirmed that the majority of data collection took place in accordance with the protocol.

Regarding the feasibility of participation in the trial, pupil comment sheets revealed a few minor issues in relation to the content of the questionnaire, but also in relation to confidentiality, owing to close proximity in class when filling out the questionnaire. It was noted by pupils that they felt that those pupil participants who were sexually active were potentially identifiable owing to the fact that they had to complete more questions, thus taking more time to complete the questionnaire.

In conclusion, the general feedback evidenced by the process evaluation component of the feasibility study was that the *If I Were Jack* intervention proved acceptable to schools and to participating pupils. Moving forward to a Phase III effectiveness trial, the research team note the consensus on excluding the homework activities, but continue to reinforce the importance of the homework piece, and so will consider offering it as an option and not a necessity. Based on the above process evaluation and that associated with questionnaire development, minor changes to the questionnaire and classroom materials will be considered, in addition to minor logistical changes associated with data collection (i.e. avoiding exam and holiday periods). Only one substantial refinement in relation to the parental component was required, which was the replacement of the teacher led face-to-face information session for parents by online videos designed to deliver the intervention to parents/guardians into their home. Fidelity of implementation of the protocol will be reinforced in teacher training sessions. The refinements were completed in 2016.

Chapter 8 Economic analysis of the *If I Were Jack* intervention and the future modelling of its cost-effectiveness

Introduction

The overall aim of the economic component was to identify the costs of delivering the *If I Were Jack* intervention and to develop a framework for assessing cost-effectiveness in a future Phase III trial. The objectives of the analysis were:

1. to identify the relevant resources used in the set up and delivery of *If I Were Jack* and their associated costs
2. to qualitatively explore the opportunity costs of delivering the intervention
3. to explore alternative methods of delivering intervention training in a future trial
4. to identify the key parameters for a cost-effectiveness analysis in a future trial.

The structure of the chapter is based around these four objectives, and the methods and results for each objective are described within each section.

Identification of the relevant resources used in the set up and delivery of the *If I Were Jack* intervention and their associated costs

Methods

We calculated the economic cost of *If I Were Jack* according to the principle of opportunity cost. That is, when resources have alternative beneficial uses (i.e. an opportunity cost), it is important to represent this with some monetary value, regardless of whether the resources were directly purchased in the market place. A microcosting approach was taken from a public sector decision-maker perspective. Relevant costs were identified, measured and valued in monetary units using the 2013/14 price year. The identification of appropriate intervention costs was guided by a number of sources. These included the practical guide to costing behavioural interventions of Ritzwoller *et al.*¹³² and methods used in other behavioural interventions such as the Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND) programme,¹³³ A Stop Smoking In Schools Trial (ASSIST)¹³⁴ and the First-aid Advice and Safety Training (FAST) parent programme.¹³⁵ In keeping with both ASSIST and FAST trials, costs were categorised according to the stage at which they were incurred in the research process: planning and preparation for delivery (stage 1) and delivery itself (stage 2).

Pre-start-up costs associated with the development of *If I Were Jack* were not included in the analysis (e.g. lesson plan development, designing of materials, DVD production²) as these are non-recurring costs that were incurred prior to the start of this study. Stage 1 costs in the *If I Were Jack* intervention covered recurring costs associated with printing the classroom materials for teachers, providing the DVD and the delivery of teacher training. As the identification of relevant resources occurred prior to the implementation of the intervention, the research team were able to record the resource use prospectively.

Stage 2 costs covered the costs associated with teacher time input for lesson preparation, printing/photocopying of worksheets and teaching, and administration time input for printing/photocopying of

worksheets. Resource use was gathered prospectively via a specifically designed Teacher Resource Use Questionnaire (see *Appendix 3*). The questionnaire had two objectives:

1. to measure the resources actually used in the delivery of each component of *If I Were Jack* in terms of time input and materials
2. to establish what teaching activities may have been displaced in order to deliver *If I Were Jack*, or, indeed, if time was freed up as a result of the intervention being implemented.

These were intended to provide us with more information on the true opportunity cost of delivering the intervention.

The quantity of resource use at each stage was multiplied by unit costs at 2013/14 prices to estimate total costs, mean cost per teacher, mean cost per school and mean cost per student. In accordance with the principle of opportunity cost, the cost of teaching time was included, as this reflects the benefits to the children forgone as a result of *If I Were Jack* being taught instead of something else. The trainer in the trial was a post-doctoral research fellow employed by the university. Training took place at schools within the staff room, so no costs were associated with the training location. Teachers were supplied with the intervention materials by the research team. The grade of teacher delivering pupil and parent components of *If I Were Jack* varied; thus, we used the mid-scale point on the upper pay scale (UPS2; Department of Education Northern Ireland).¹³⁶ We assumed that a clerical officer at point 11 on the National Joint Council pay scale carried out the photocopying of classroom materials when the teachers did not. All staff costs included 24% for employers' costs.

Results

Stage 1 resource use and costs

The key resources identified for the planning and preparation stage (stage 1) are presented in *Table 42* along with their costs. The costs are based on the training of 16 teachers and the participation of 420 students at baseline in the intervention group.

Stage 2 resource use and costs

The key resources identified for the delivery of the classroom lessons and the information evening along with their costs are presented in *Table 43*. Two of the 16 teachers who were trained were not involved in the delivery of the intervention. Teachers delivered either the classroom component or the information evening. The costs are therefore presented as total costs and mean costs per teacher based on the responses from the Teacher Resource Use Questionnaire of the 12 teachers who delivered the classroom component and the two teachers who delivered the information evening.

The total costs of the *If I Were Jack* intervention for the feasibility study are presented in *Table 44*. Stage 1 costs were apportioned to the teachers delivering the intervention. This allowed a cost per teacher and a cost per school to be calculated. Cost per pupil was calculated by dividing the total cost for each school by the number of pupils at that school participating at baseline. It can be seen that in the feasibility study the mean cost per school and per pupil after adjusting for school as the cluster was £1275.42 and £13.66, respectively.

A qualitative exploration of the opportunity costs of delivering the intervention

When resources are allocated to be used in a particular way, they are no longer available to be used in another way. As a result, any benefits that would have been received are forgone. The opportunity cost is the term used to reflect the value of the benefits that have been forgone. Although costing the resource use as detailed in objective 1 is a pragmatic approach to measuring this opportunity cost, we wanted to explore the potential sacrifices more directly via the teachers.

TABLE 42 Resource use and associated costs of planning and preparing for *If I Were Jack*

Resource use	Cost details ^a	Unit cost (£)	Number of units	Total cost (£) over four schools
Classroom materials (master copies)	First 10 copies £82.65 (£39.15 for each additional 10 copies)	6.09	16 copies	97.42
Instructions for teachers	First 10 copies £46.76 (£8.70 for each additional 10 copies)	2.77	16 copies	44.37
Parent and guardian discussion guide	First 10 copies £46.76 (£8.70 for each additional 10 copies)	0.92	16 copies	44.37
Parent and guardian information sheet	Assume £0.10 per double-sided black and white page	0.10	420 copies	42.00
DVD	£1 per copy for 300 copies (price changes depending on volume ordered)	1.00	16 copies	16.00
Total cost of materials (£)				244.16
Training sessions	Four groups sessions and 1 individual session took place	N/A	5 sessions	0.00
Teacher	Rate per hour = (salary + 24% employers cost)/195 days × 6.5 hours a day. Salary = UPS2 £35,801	35.02	16	560.39
Disposable course materials [PowerPoint slides (Microsoft Corporation, Redmond, WA, USA)]	Assume £0.10 per double-sided black and white page, 6 pages	0.30	16 copies	4.80
Location and associated cost (e.g. room hire)	All based in school classrooms/staff room	N/A	N/A	0
Food and refreshments	None provided	N/A	N/A	0
Total cost of training				565.19
Stage 1 planning and preparation for delivery subtotal				809.35
N/A, not applicable.				
^a Cost estimates obtained from trial team or the appropriate salary scale as specified in <i>Methods</i> .				

Methods

As stated previously, another objective of the Teacher Resource Use Questionnaire was to establish what teaching activities may have been displaced in order to deliver *If I Were Jack*, or, indeed, if time was freed up as a result of the intervention being implemented. Responses to the relevant questions were collated and summarised.

Results

Of the 14 teachers involved in the delivery of the intervention, 12 delivered the main classroom component and two delivered the parents'/guardians' information evening component. In the feasibility study, no teacher delivered both.

When teachers were asked what they would normally have been doing during the time they spent being trained to deliver *If I Were Jack*, 11 of the 14 teachers responded. Ten out of the 11 teachers indicated that they would have been preparing for lessons and marking; two of these teachers specifically mentioned sex education lessons and two mentioned PC. One of the 11 teachers stated that they would have been doing personal study.

When asked what they would have been doing in the time they spent preparing to deliver the lessons, all 12 of the 14 teachers involved in delivering the lessons stated that they would have been preparing for

TABLE 43 Resource use and associated costs of delivering *If I Were Jack*

Description	Resource use	Cost details	Unit cost (£)	Total time (hours)	Total cost (£)	Mean (SD) cost per teacher (£)
Delivery of classroom intervention (n = 12)						
Teaching time		Rate per hour = (salary + 24% employer's cost)/(195 days × 6.5 hours a day). Salary = UPS2 £35.801	35.02/hour	31.50	1103.13	91.93 (44.25)
Preparation time ^a				26.67	933.87	77.82 (62.15)
Other time				2.67	93.39	7.78 (13.24)
Printing/copying ^a of classroom materials by teacher				2.33	81.71	6.81 (9.58)
Printing/copying of classroom materials by clerical officer ^a		Mid point rate per hour = £7.93 + 24% employers cost = £9.83/hour	9.83/hour	5.29	65.58	5.47 (5.28)
Classroom materials (printing/photocopying)		Assume £0.05 per single-sided black and white page, 20 sheets in total	0.05	–	1154.00	96.17 (44.99)
Delivery of information evening component (n = 2)						
Teachers' delivery time	As above		As above	2.00	70.04	35.02 (0)
Preparation time				2.25	78.80	39.40 (6.19)
Other time				3.00	105.06	52.53 (24.76)
Other staff time ^b	Varied			1.50	600.22	300.11 (417.47)
Printing/copying of classroom materials by clerical officer	As above		As above	0.67	6.55	3.27 (2.32)
Stage 2 delivery of intervention subtotal (n = 14)					4292.34	357.18 (75.24) ^c
<p>a Teachers did not always provide preparation and photocopying time when they taught multiple classes for the same lesson. For this analysis, the assumption was made that the same time was required for each class.</p> <p>b One teacher reported input by an administrator and one reported input from a VP. For the latter, the mid-point of leadership scale was used to estimate hourly rate.</p> <p>c Mean (SE) adjusted for school as the cluster.</p>						

TABLE 44 Total costs for the *If I Were Jack* intervention in the feasibility study

Description of costs	Cost (£)
Stage 1 planning and preparation for delivery	
Materials	244.15
Training	565.19
Stage 1: total ^a	809.34
Stage 2: delivery total ^b	4292.34
Overall total ^c	5101.68
Mean cost per teacher (SE) ^d	364.41 (75.24)
Mean cost per school (SE) ^d	1275.42 (341.32)
Mean cost per pupil (SE) ^d	13.66 (4.51)
<p>a Based on 16 teachers trained and 420 intervention pupils at baseline.</p> <p>b Based on 14 teachers who delivered the intervention.</p> <p>c For four schools.</p> <p>d SE presented and adjusted for school as the cluster.</p>	

other lessons. Two specified sex education lessons, two specified RE, two specified PC and one specified that the lesson would have been for the LLW module.

When asked what they would normally have been doing during the time they spent delivering the lessons for *If I Were Jack*, all 12 of the 14 teachers stated that they would have been delivering other lessons, six specified PC lessons, three specified sex education lessons, two specified RE lessons and one stated that they would have been delivering a lesson from the LLW module.

Only two teachers delivered the parents'/guardians' information session. When asked what they would normally have been doing during the time they spent preparing for this session, both responded that they would have been doing work-related activities. When asked what they would normally have been doing during the time they spent delivering the information session, one responded work-related activities and the other responded non-work/leisure activities.

All 14 teachers were asked if they felt that anything had been sacrificed which would have been of benefit to pupils because of the time spent using *If I Were Jack*. Thirteen teachers provided a response, with 11 stating 'No' and two stating 'Yes'. Only one of the teachers who said yes provided more information to say 'Some of the pupils did start to think how their lives would change – problems, parents'. On reflection, this information suggests that the teacher should have responded 'No' (i.e. nothing had been sacrificed). Indeed, it suggests that something had been gained in that, from the teacher's perspective, the intervention had helped the pupils to think about the consequences of an unintended pregnancy in their lives.

The final question asked teachers if they felt that by using *If I Were Jack* they had saved time normally spent looking for RSE resources/planning RSE activities. Twelve of the 14 teachers provided a response: 11 said 'Yes' and nine of these provided further information. In general, the responses indicated that teachers felt that the resources were 'effective', 'well-planned' and 'up-to-date' and that they saved time that would have been spent searching for relevant activities and alternative sex education resources. The one teacher who did not think that the intervention had saved them time did not provide any further information.

Exploration of alternative methods of delivering intervention training in a future trial

In this feasibility study the intervention was delivered to four schools by a university researcher with a total of 16 teachers involved. Even with this relatively small number of schools and teachers, the organisation of teachers' training sessions proved difficult. Principal barriers included identifying a time that suited both teachers at each school and the researcher delivering the training, and finding a suitable venue for the training within the school. These issues would only be exacerbated by increasing the number of schools and teachers, which would be required for a future Phase III trial. We also acknowledge that using a university researcher to deliver training on a large scale may not be realistic. Thus, using scenario analyses we explored alternative approaches to training for a future Phase III trial in order to estimate the financial impact of the alternatives.

Methods

We constructed realistic scenarios of alternative methods of delivering the training by varying the following parameters: the training venue, provision of teaching cover, mode of training delivery and the trainer. For each scenario we estimated the total costs for each stage of the intervention [i.e. stage 1 (planning and preparation for delivery) and stage 2 (delivery)]. Based on the feasibility study results at follow-up 1, it was estimated that 25 intervention schools, 100 teachers and 2625 pupils would be required in a Phase III trial. The cost of materials (stage 1) was therefore calculated by increasing the quantity of units from the feasibility study accordingly, and then multiplying the quantities by the unit costs observed in the feasibility study. Training costs were calculated based on the details specified in the scenario. Mean cost per teacher, mean cost per school and mean cost per pupil were also calculated for each scenario.

Scenario 1

In the feasibility study training was delivered over lunch breaks or in free periods. In scenario 1 we explored the financial impact of providing cover by a supply teacher for teachers to attend training delivered by a non-government-funded facilitator within their own school at an estimated rate of £250 for a half day. It was assumed that a half day (3.25 hours) of teaching cover would be required based on the recommendation of the National Association of Schoolmasters Union of Women Teachers, one of the largest teachers' unions representing teachers across the UK.

Scenario 2

In scenario 2 we explored the financial impact of teachers attending group training sessions delivered by a non-government-funded facilitator in a hired venue such as a hotel. This method was recently employed with success in the Steps Towards Alcohol Misuse Prevention Programme (STAMPP) trial (ISRCTN47028486). We hypothesised the need to hire venues across the UK on six occasions for a Phase III trial. In common with scenario 1, this would require the provision of teaching cover for a half day. We used the hotel costs observed in STAMPP for a whole day of training (£25 per head) and divided this by two to obtain a half day training cost (£12.50 per head).

Scenario 3

Teachers' views on future training approaches were gathered as part of the process evaluation (see *Chapter 7*). Feedback indicated that face-to-face training was potentially not necessary owing to the programme materials being so comprehensive. Therefore, in this scenario we explored the impact of delivering training via 25 separate 60-minute webinars. We assumed that teachers at each school connected to it as a group and not individually in their own time. It was also assumed that teaching cover would not be needed. We used the cost associated with the delivery of 25 separate 60-minute web conferences with audio via British Telecom (BT) Conferencing (BT Group plc, London, UK) for the public sector at a rate of 13 pence per minute (0.04 pence for audio, 0.09 pence for web) per connection (host and school). A total cost estimate of £390 was obtained via personal communication with a BT Accounts Manager.

Results

The results of the scenario analyses for a Phase III trial are also presented in *Table 45*. The highest teacher training costs were associated with the use of hotels to host the training events and a facilitator to deliver the training (scenario 1). The lowest costs were associated with the use of webinars delivered at a school level (scenario 3).

Identifying the parameters for a cost-effectiveness analysis in a future trial

The aims of this section are to:

- provide a framework for an economic model that would encompass the future impacts on costs and outcomes (both health and social outcomes) as a result of engagement with the *If I Were Jack* intervention
- use this framework to outline needs and possible sources for data to populate any such model as may be constructed in the future.

The word 'framework' is important. What is presented is not an 'economic model' as such, and there has never been an intention within the current study to conduct a modelling exercise. Rather, it is the feasibility of conducting such an exercise that is being assessed and presented.

The framework: from trial outcomes to social outcomes

Owing to the social impacts of many interventions, especially public health interventions, extending beyond the life of any single randomised trial, it is often the case that funders and decision-makers are interested in 'modelling' what these future impacts – usually expressed in terms of costs (to reflect net resource impacts) and benefits (to reflect future impacts on health and other aspects of well-being) – might be.

TABLE 45 Scenario analyses for a Phase III trial

Description of costs	Scenario 1: cost of teaching cover provided for training in schools delivered by a facilitator (£)	Scenario 2: cost of teaching cover provided for group training in hired venues delivered by a facilitator (£)	Scenario 3: cost of webinars delivered into schools (£)
Stage 1: planning and preparation for delivery			
Materials ^a	1525.95	1525.95	1525.95
Training ^b	11,412.82	12,662.82	3922.41
Stage 1: total	19,188.77	15,688.77	5,448.36
Stage 2 delivery: total ^c	30,659.57	30,659.57	30,659.57
Overall total	49,848.34	46,348.34	36,107.93
Mean cost per teacher	498.48	463.48	361.08
Mean cost per school	1993.93	1853.93	1444.32
Mean cost per pupil	18.99	17.66	13.76
<p>^a Quantity of units scaled up for larger trial and multiplied by unit costs used in feasibility study.</p> <p>^b Based on details specified in the scenario.</p> <p>^c Total stage 2 costs observed in the feasibility study were divided by the 14 teachers and multiplied by the 100 teachers anticipated in a Phase III trial. Based on the feasibility study results at follow-up 1 it was estimated that 25 intervention schools, 100 teachers and 2625 pupils would be required in a Phase III trial. The cost of materials (stage 1) was therefore calculated by increasing the quantity of units from the feasibility study accordingly and then multiplying the quantities by the unit costs observed in the feasibility study. Training costs were calculated based on the details specified in the scenario. Mean cost per teacher, mean cost per school and mean cost pupil were also calculated for each scenario.</p>			

For the *If I Were Jack* intervention, we have attempted to map out the important events subsequent to engaging with *If I Were Jack*. This is presented in *Figure 6*, along with the consequent data needs and possible sources of such data. Some of the required data can be sourced from a trial, whereas other data would have to be sourced from elsewhere.

The framework in *Figure 6* should be read from left to right and, thus, starts with a defined population that would engage with the intervention. The boxes represent events, or collections of events, that could have well-being and/or resource consequences. Data needs associated with the boxes are displayed at the top of the framework and labelled 'Information requirements: events'. So, for example, all one would need to know at the stage of engaging with the intervention are the costs of the *If I Were Jack* intervention.

The lines between the boxes represent changes in rates at which the events might occur, and the data needs associated with these (at the bottom of *Figure 6*) are labelled 'Information requirements: changes in rates of occurrence'. For these rates, 'x' and 'y' should always sum to 100, as they represent percentage amounts by which the original population, and subsequent sub-divisions of that population, is spread across the set of events occurring in the next stage of the framework. The subscripts on 'x' and 'y' simply represent the progressing stages to which our 'x' and 'y' values apply.

For example, an important secondary outcome from the trial is likely to be related to 'awareness raising'. Awareness is regarded as an important secondary outcome because it is believed to mediate the primary behavioural outcome of safe sexual intercourse/no sexual intercourse. For a certain percentage of the targeted population (x^1), awareness will be raised, whereas for a corresponding percentage ($y^1 = 100 - x^1$), there will be no such impact. Trial data would indicate what these percentages might be and, for any individual who is positively influenced, what the magnitude of the change in awareness might be. For those whose awareness is not raised, we might assume that they revert to baseline rates for future events as we move from left to right in *Figure 6*. These rates are merely indicated by the word 'baseline' (issues related to 'baseline' data are discussed below).



More positively, however, any raised awareness might subsequently lead to changes in behaviour. It is important to note that such changes might conventionally be seen as leading to greater abstinence and increased condom use. However, a more positive outlook might be to view increased awareness as leading to increased confidence with respect to decision-making about sex. This might lead to increased condom use, but is better expressed as leading to increased levels of contraceptive use. Alongside abstinence, we need also to think of 'delay' of sexual intercourse and 'frequency'. For these, we would need to know how higher awareness relates to changes in contraceptive use, delay and frequency behaviours, that is, values for x^2 and y^2 – which could be obtained from a subsequent trial and for which there is an existing literature (see *Chapter 3*).^{19,21–23,25}

We would also require data on the costs of contraceptive use, including condom use. Once again, for those going down the ' y^2 ' pathway, we might assume that they revert to baseline from that point onwards.

The fact that programme participants might feel more in control of their sexual behaviour and decision-making, of course, has value in and of itself. However, the next stage would also involve estimating the extent to which increased contraceptive use (and changes in delay and frequency) relates to more immediate (health) events. For each of these, a separate value of x^3 (and, correspondingly, y^3) would be required. These events would be as follows:

- STIs, for which data would be obtainable from a trial as well as literature linking contraceptive use, delay and frequency changes to STI occurrences^{137,138}
- pregnancies before the age of 17 years²⁵
- terminations associated with pregnancies, for which we would require data on which to base an assumption about the continuation, and corresponding termination, rates.

For each of these, we would require data on costs (of a STI, a delivery and a termination) and we would have to make assumptions about what costs to include (e.g. do we go as far as counting the lifetime costs of a birth and what assumptions do we make about replacement; that is, does an early birth now replace another birth that might have happened later?).¹³⁹ We would also require data on health-related quality of life and other health outcomes associated with STIs, pregnancy and termination.

The final set of events in *Figure 6* comes under the general heading of 'life chances'. Once again, we would require estimates of the percentages x^4 and y^4 ; essentially, for what proportion of people are life chances negatively impacted by an early pregnancy? The impact of such an event is portrayed currently in terms of withdrawal from education and the consequent effects of that on increased welfare payments and worse job opportunities, for which we think there are data available from government sources in NI. On the basis that a teenage pregnancy effectively withdraws the mother from the labour market for at least 18 months, the DHSSPS estimates that the cost of a teenage pregnancy to the Exchequer (unemployment benefits and administration, plus tax revenue forgone) stands at £20,000 per mother.²⁶ In 2006, it was estimated that teenage pregnancy costs the NHS £63M per year.¹⁴⁰ In 2009–10, £26M was paid in benefits to teenage mothers on income support (England and Wales-based data).¹⁴¹ Other adverse sexual health outcomes also cost the NHS large sums. For example, it is estimated that the UK spends between £700M and £1B per year treating STIs and their sequelae.^{142,143}

Other data needs: the 'baseline'

Depending on the 'level' addressed by the modelling, and in order to address the issue of the 'baseline' for many of the variables, other requirements might be for NI-level data – for example, things like current rates of condom use and abstinence, and for STIs, age-specific pregnancies and associated terminations, as well as data on withdrawals from education.

Discussion and conclusions

The economic analysis provides a detailed breakdown of the recurring costs that were incurred in the planning, preparation and delivery of the *If I Were Jack* intervention in the feasibility study. The identification of potential resources prior to implementing the intervention allowed the data to be collected prospectively, thus maximising the accuracy of the estimates. The total cost to deliver the intervention was estimated to be £5101, equating to £1275 per school and £14 per pupil. The scenario analyses revealed that the inclusion of formalised teacher training sessions for a future trial could range from £14 per pupil when webinar-based training is used, to £19 per pupil if face-to-face training delivered by a facilitator within schools is adopted. Information gleaned from the process evaluation (see *Chapter 7*), however, suggested that face-to-face training may be more efficacious in engaging the teachers and generating better fidelity to protocol in terms of implementation. Thus, the cheapest option may not be the best approach for a future Phase III trial.

It must be highlighted that these estimates are based on the delivery of the intervention in a trial setting. If the intervention were to be mainstreamed, then other costs would need to be considered, including those associated with 'train the trainer events', updating the intervention materials, or making the interactive DVD region specific. Likewise, some aspects of the costs may decrease over time. The costs reported in the scenario analyses reflect the cost of introducing and delivering *If I Were Jack* on one occasion. In reality, once teachers have been trained they would not need to be retrained on an annual basis, requiring only, at most, refresher training. Therefore, the cost per pupil would fall when there is no staff turnover.

The overall conclusion that can be drawn from the qualitative exploration of the opportunity costs of delivering the intervention is that *If I Were Jack* ultimately saved teachers time, which would otherwise have been spent preparing for or delivering lessons within the same or related curriculum module. Perhaps most importantly, teachers did not feel that anything that would have been of benefit to pupils had been sacrificed because of the time spent using *If I Were Jack*. The methods of cost evaluation (questionnaires provided in advance and follow-up interviews) provided an additional insight into the implementation of RSE in schools (business as usual) and specifically this intervention. In a future trial, we would repeat data collection on cost estimates, to see if there are any changes over time and over space (the rest of the UK) and also because this analysis not only informs economic analysis but also the implementation of the intervention more broadly.

Finally, if an analysis of longer-term impacts beyond the life of a trial was required, we have provided a framework for how this might be approached and have assessed how trial data might inform parts of such a framework in combination with data gathered from published and other public sources.

Chapter 9 Summary and conclusion

Introduction

The purpose of this chapter is to summarise the main findings of the study. It will be structured in the following way. First, we begin by outlining some of the limitations of this study. Second, we summarise the findings in relation to the study aim and objectives. Third, we summarise the findings in relation to the prescribed progression criteria to a larger effectiveness trial. Finally, we summarise how these findings might add to the emerging literature relating to the evaluation of RSE interventions in schools along with suggestions for future research.

Study limitations

In this exploratory trial we assessed the feasibility and acceptability of an effectiveness trial of *If I Were Jack*. The study was therefore designed to generate learning that could inform the decision about whether or not to proceed with an effectiveness trial, and also – if a decision to proceed was made – learning in relation to optimising the design and implementation of an effectiveness trial. Nonetheless, although this study was a learning exercise, the study itself also has a number of limitations that should be borne in mind when interpreting the results presented in this report.

Systems for identifying schools

A total list of all eligible schools in NI was sought for this trial. However, we did not use this as part of our recruitment strategy. Instead, we presented the research at RSE training days for teachers and then created a convenience quota sample, based around the voluntary participation of schools that met our inclusion criteria. The advantage of this approach is that it proved to be an efficient and effective method of achieving a stratified sample of schools. The disadvantage is that the non-random nature of the selection of schools means that the data cannot be said to be representative of schools in NI. In a future trial, we would send an invitation letter to all eligible schools in the defined areas. In addition, we would use two networks to help with school recruitment in defined areas: the Wales School Health Research Network, which is a network of secondary schools across Wales and South West England led by the Centre for the Development and Evaluation of Complex Interventions for Public Health Improvement, Cardiff University, in a partnership with Public Health Wales and the Welsh Government; and the University College London Partners, School Health and Wellbeing Research Network. Although these networks do not encompass all schools in the relevant area, they will help the trial to extend its reach, while also being an efficient approach to recruitment.

Feasibility of collecting follow-up data in secondary schools at 12–14 months

We did not plan to conduct long-term follow-up of pupils of > 1 year (as would happen in a future effectiveness trial), as this would be unfeasibly costly for an exploratory trial and would cause unnecessary delay to the ultimate goal of an effectiveness trial.

Pupil recruitment rates

Pupil recruitment rates at baseline were just above our threshold of 80%. This rate was affected by 9% of absenteeism in schools and 10% of withdrawal from our study. We did not have good information on the characteristics of pupils who were not present on the day of baseline data collection. However, we learned valuable lessons about the reasons for parental and pupil withdrawal and how participant withdrawal might be averted in future trials through improved pupil information sessions and clearer information for parents.

Intervention acceptability to parents

We did not learn as much as we might have about this aspect of the study because we failed at the first fence, as it were, in terms of engaging parents with the parental information sessions. We did, however, begin to test our hypothesis that online delivery methods would work better with parents during a main trial and better understand some of the strategies for reaching parents online.

Delivery of an interactive video drama

Technical difficulties, mostly associated with school internet networks, also led to all but one school showing the IVD via overhead projector as opposed to on individual computers. Process evaluation findings revealed, however, that the use of overhead projectors was an acceptable means of delivery for both teachers and pupils, with most acknowledging that there were additional benefits to delivering the intervention in this way (i.e. ability to control the pace, an opportunity to stop and explain words or questions and being better for pupils with reading difficulties). In a future trial we would still encourage use of individual personal computers or tablets and we would seek to build in a mode of delivery into the memorandum of agreement. However, owing to the positive evaluation of the overhead projector modality, we would not exclude a school if this was the only feasible means of delivery.

Electronic data collection

We piloted the use of electronic data collection against data collection using traditional paper forms. Electronic data collection failed owing to technical difficulties caused primarily by a lack of competence on behalf of the company we hired to develop the online data collection tool. Following several investigations, the company concluded that the problems were due to conflicts with saving the data on a cloud server; however, they were unable to resolve the issues within the timeframe of the study. We therefore did not have an opportunity to thoroughly investigate the other advantages and disadvantages of electronic data collection. However, in schools in which online data collection did work, pupil and teacher feedback was positive.

Pupil confidentiality and independence while completing questionnaires

Although data collection was generally administered under 'exam conditions', with teachers remaining in the classroom and fieldworkers supervising data collection, the layout of many of the classrooms meant that pupils were in close proximity. Fieldworker observations suggested that, in some cases, pupil independence and confidentiality may have been compromised. It is difficult to say what effect this may have had on data quality but it provided valuable lessons for planning data collection in a main trial.

Missing data

We had high rates of missing data in relation to questions on STIs, which, we have surmised, was likely to be due to the fact that pupils ignored this question if they had not had a STI diagnosis. Although we would still use this question again as part of an overall health economics evaluation in a main trial, with prompts to reinforce relevance, caution needs to be applied to the results of this question in the current study.

Data linkage

We did not test the feasibility of conducting data linkage of our feasibility study data with health and social care records of teenage conceptions, because such data linkage is not possible in NI, owing to the fact that the NI health service does not collect conception data as part of health records. In a future effectiveness trial, we would ask participants if they would be happy to provide personal information to allow the research team to follow them up with questionnaires relating to fertility and sexual health in the future.

Generalisability of the acceptability of the intervention

This feasibility trial tells us only about the acceptability of this intervention in one country of the UK, namely NI. However, during the course of the feasibility trial we conducted a separate 'transferability study'^{144,145} to assess the acceptability of the intervention in the other countries of the UK. Summary results are presented below (see *Criteria for progression to main trial*).

Generalisability of the trial methods across the UK

Although we did not test our methods UK wide, a thorough literature review on all aspects of our methods allows us to interpret applicability across the UK.

Fidelity to implementation of the protocol

Achieving total fidelity to implementation of the protocol is very difficult in schools-based research where skilled teachers are delivering the intervention. Although we recorded where teachers made adaptations to the intervention protocol, we did not link these data with pupil outcomes.

Intention to treat

Randomised controlled trials often suffer from two major complications – non-compliance and missing outcomes.¹⁴⁶ ITT is used as the most unbiased way of analysing a trial, and this was the statistical approach undertaken in this feasibility study. In order to assess the necessity and appropriateness of utilising the ITT approach, full reporting of any deviations from random allocation and missing response is essential, as reinforced in the CONSORT guidelines on the reporting of RCTs.^{128,147} The ITT approach can be optimised if complete outcome data are available for all randomised subjects in order to determine the per-protocol population, defined as the subset of the ITT population who completed the study without any major protocol violations. In this feasibility study we were unable to determine which participating pupils randomly allocated to the intervention group were actually in receipt of the intervention. We assume that the percentage of compliance was high, because pupil attendance in class was consistently high throughout the intervention period, but we are unable to report on actual numbers. Moving forward to a Phase III effectiveness controlled RCT, potential solutions worth considering would be to insert a question at the beginning of the follow-up questionnaire to ascertain whether or not participants have viewed the IVD and participated in the other relevant intervention activities. Alternatively, pupils who have not been in receipt of the intervention post baseline could be instructed not to take the follow-up questionnaire.

Summary findings relating to study aims and objectives

Primary aim

The aim of the study was to determine the value and feasibility of conducting an effectiveness trial of the *If I Were Jack* RSE intervention in post-primary schools.

We now break down the main findings of the study under the study objectives.

Secondary objectives

To assess the acceptability of the intervention to schools (principals and RSE teachers), male and female pupils and parents.

The intervention proved to be acceptable to schools (principals and RSE teachers), as evidenced by the very favourable remarks by teachers and school principals right across all participating schools.

I think, as resources go, it's one of the best I've seen out there because anything we have is quite ancient, dated or from, like . . . England, Australia . . . We're very lucky to have a resource that is very current and set, you know, in the local area.

I think it's actually a very good resource, and I think the fact that it's coming from a boy's point of view is unique and the pupils took to that well, you know, because they're always hearing about teenage pregnancy always more geared from the girl's point of view. So, I think they found that maybe kind of . . . made them more interested in it, just from the very start.

If I Were Jack was also an acceptable intervention for pupils, both male and female. Pupils commented on specific positives of the intervention and these included that it was 'locally set', 'realistic', 'relatable', 'interesting', 'informative' and 'helpful'.

It didn't give you one point of view, it gave you many, and it gave you the way that he was worried, and that she was worried. It didn't show you everything would be fine.

Male

Like, if it was to happen to someone, it's kind of a difficult situation to deal with and it shows you that. It's almost like em . . . you get a first-hand experience of what would happen and it's scary.

Female

In relation to parents, the low rate of parental/guardian withdrawal of children from the study (6.8%) suggests that the vast majority of the parents were happy for their child to participate in the intervention and the associated research. However, the results also suggest that parents were not willing to participate themselves in the intervention in the planned way (i.e. in a face-to-face information session about the intervention). Thus, a key change to the intervention, which we will undertake as a result of this feasibility trial, is to change the face-to-face information sessions to an online format. The parental component of the intervention will instead be delivered through three short (< 5 minute) online videos to parents. The links for these videos will be texted and/or e-mailed (with one additional reminder) by participating schools to all parents/guardians of the intervention year group on school communication lists. This electronic communication approach was successfully piloted in the feasibility study. Recent studies^{68,69,148} demonstrate the importance of embracing such 'education entertainment' modalities as engaging adjuncts to school-based education. This refinement has been funded by the Health and Social Care Research and Development Office of Northern Ireland (HSC R&D). It was completed in 2016 and we would plan to pre-test this approach as part of a main trial.

Another secondary objective was to identify optimal delivery structures and systems for the delivery of the resource in the classroom. Teachers valued the fact that they considered *If I Were Jack* to be an 'off-the-shelf' product that required little preparation time, apart from some familiarisation with the content and photocopying. Teachers indicated that if the resource was being made more readily available outside the research environment, then teacher training could become accessible online, with a contact number to address any enquiries. They did, however, acknowledge that, in the context of participation in a research trial, a researcher-led session was essential to reinforce fidelity of implementation, etc. The evaluation also revealed that more time could have been dedicated to the teacher training session, as teachers reported a lack of time to address all questions.

Process evaluation indicated that there would be advantages to conservatively forewarning teachers of the time requirements of component elements of the intervention, thereby enabling forward planning (i.e. avoid using last lesson session of the day). One school had a 35-minute lesson time and struggled to complete the IVD and other accompanying activities within a single lesson, as hoped. Time-related issues were prevalent, with teachers reporting incidents such as examinations running over time and pupils being unable to complete questionnaires because school had ended for the day and they had to race off to catch their buses. Teachers valued the presence of the research team and the assistance made available through classroom assistants. Pupils valued incentives, such as sweets, but some suggested that a 'contraceptive goody bag' might be better.

Finally, in relation to the delivery of the intervention in the classroom, there was a consensus that pupils were receptive to teachers as deliverers of the intervention. However, process evaluation findings also revealed that some pupils had an aversion to engaging with parents in the homework activity, in addition to an actual or perceived perception that their parents would not be willing to engage in the homework activity with them. Although teachers reported that some students did undertake the homework activity, this was regarded by the teachers as an optional bonus, rather than a requirement. Thus, for a future trial we must consider the necessity of this 'beyond classroom' component to the overall logic model of the intervention.

As detailed above, technical difficulties meant that the questionnaire was delivered predominantly in paper form. Technical difficulties, mostly associated with school networks, also led to all but one school showing the IVD via overhead projector as opposed to online. Process evaluation revealed this was an acceptable method of delivery, with most teachers acknowledging that there were additional benefits to delivering in this way (i.e. control of pace, the opportunity to stop and explain, and being better for pupils with reading difficulties). In a future trial, we would still encourage use of individual personal computers or iPad (Apple Inc., Cupertino, CA, USA) computers, and we would seek to build in a mode of delivery into the memorandum of agreement. However, owing to this positive evaluation of overhead method, we would not exclude a school if this was the only feasible way of delivery.

A further secondary objective was to establish participation rates and reach, including equality of engagement across schools of different socioeconomic and religious types. The study demonstrated that it was feasible to recruit the full range of the most common types of schools in NI, namely schools with differing school management systems, including faith-based schools, schools that are especially academically oriented and those that are not, and schools that are in socially deprived as well as socially affluent areas. The inclusion of faith-based schools is important because we believe that this is the first RSE intervention trial to include faith-based schools in the UK and > 50% of schools in NI are faith based. Nonetheless, we also learned that the hardest schools to recruit for this trial were schools that were both faith based (i.e. RC) and high academic achieving schools. These are what are known as 'Catholic Grammar Schools' (RC Grammar) in NI. The overall recruitment rate for RC schools was 30%. However, the recruitment rate for RC grammar schools was 13%, while the recruitment rate was 67% in RC maintained secondary schools. The latter are RC schools for which the pupil's entry selection is not dependent upon high academic achievement at 11 years of age. Thus, although the trial succeeded in recruiting a breadth of schools across crucial sociodemographic criteria, we are acutely aware that we also then need to reach potentially socially excluded groups of pupils within these schools, those students who are most likely to become a teenage father/mother (e.g. those from more deprived groups, those with low literacy, low attainment and poor school attendance, and those with learning disabilities), and we address this in the discussion below.

Another secondary objective aimed to assess trial recruitment and retention rates. In terms of school recruitment, the feasibility study demonstrated that our target aim of recruiting seven schools, four to the intervention arm and three to the control arm, was realistic and that we could achieve our school recruitment target rate (target = 25%, achieved 37%). In terms of pupil recruitment, the target was also met, with an overall pupil recruitment rate of 80.9%. Absentees who did not return completed questionnaires accounted for 9% of non-participants, and parental and pupil opt-outs accounted for the remaining 9.9% (6.8% and 3.1%, respectively). However, one conclusion of the trial has been a commitment to work with the trial steering group in the main trial to enhance clarity around the consent process for parents and guardians, as some indicated confusion regarding the opt-out form (assuming it was an opt-in form). Pupil information sessions also need to be better monitored by researchers to ensure that they follow protocol. We shall consider a short audio-visual presentation, which could be easily shown by teachers in addition to information sheets. In addition, we would try to avert data loss to pupil absenteeism by not conducting data collection on Monday mornings or Friday afternoons or in the weeks preceding holiday periods. In terms of parental recruitment, as reported above, we failed to adequately engage parents in the study (parental information sessions), recruiting only 2.3% of all parents/guardians. The recruitment of teachers for semistructured interviews within schools was unproblematic. Retention of schools was successful (100%) as was retention of pupils (93.1%).

We also aimed to assess variation in normal RSE practice across the participating schools. In this feasibility study, existing provision of RSE (content, frequency, co-ordination and delivery) was assessed. In NI there is no official curriculum material targeted to Key Stage 4 (Years 11–13). Year 11 was the participating year group in this feasibility study, although there was a consensus among participating teachers that they would also like to use the intervention with Year 10. In general it emerged that RSE provision was extremely variable and not perceived as a priority subject. Some schools had well-structured RSE programmes, whereas others had difficulty articulating the RSE provision within the school. Pupils recalled little to no attention or emphasis placed on UTP. All schools provided most of their RSE provision using the 'Insync' Personal

Development programme, developed by CCEA, of the LLW statutory component of the NI curriculum. This programme was developed for Key Stage 3 to be targeted to Years 8–10 (see *Appendix 7*). Although RC schools described their approach as always in line with the RC Church's teachings and ethos, this did not appear to alter the nature or attitude towards RSE provision compared with non-Catholic participating schools. Participating grammar schools, although academically focused, were not distinguishable in their existing RSE provision. Teachers reported a general sense that RSE provision remained somewhat sensitive and controversial and that attitudes towards RSE were highly variable, with some reports of religious conservatism and homophobia, and that improvements could be made. There was unanimous willingness to embrace new approaches and improve existing provision. Post-qualification training and opportunities for training for teachers appeared to be all but absent.

A further secondary objective was to refine the survey instruments as a result of cognitive interviews with male and female pupils. The pupil questionnaire has already undergone substantial redevelopment, as informed by the pilot and feasibility study (detailed in full in *Chapter 4*). Based on cognitive interviews (and other feedback mechanisms such as the pupil comment sheets and fieldworker observation sheets) after the final data collection in the feasibility study, we determined that further changes to the pupil questionnaire were required. These included simplifying and standardising the Likert-scale options and increasing the privacy of the participant by ensuring that skipped sections would be replaced with an equivalent number of questions and by randomising sections that would be incorporated into the questionnaire for a Phase III effectiveness trial. This was suggested by pupils so as to disguise who was answering what questions at any particular time point during data collection sessions, thereby negating any presumptions being made by fellow pupils about sexual activity and time taken to answer certain questions as a result. For an overview of the suggested changes to the questionnaire that emerged from the focus group activity see *Table 17*.

We also aimed to assess differences in outcomes for male and female pupils. In the subgroup analysis of the primary outcome measure by gender, there was an improvement in boys in the intervention arm (2.2% improvement at follow-up 1 and 0.5% improvement at follow-up 2), but a deterioration in females in the intervention arm was evident (1.3% deterioration at follow-up 1 and 4.4% deterioration at follow-up 2). Female pupils in the intervention group scored notably higher than their male counterparts in the Knowledge scale at both follow-ups 1 and 2; in the Intentions scale at follow-up 1; in the Intentions Self-Efficacy subscale at both follow-up 1 and 2; and in the Attitudes subscale at both follow-ups 1 and 2. Male pupils in the intervention group scored significantly higher ($p = 0.004$) than male pupils in the control group at follow-up 2 and notably higher than their female counterparts in the intervention group in the Male Role Attitudes scale (male 1.27, 95% CI 0.41 to 2.13; female 0.47, 95% CI -0.22 to 1.17). This was not evident at follow-up 1. The Male Role Attitudes scale is essentially an analysis of emerging masculinities that are more gender equal versus the traditional gender-related views that men and women are unequal.

The questionnaire also included a specific attitudinal question relating to whose responsibility it was to prevent an UTP, allowing for the balance of responsibility to be moved towards males or females. Both the intervention and control group demonstrated an improvement towards attributing an equal 50 : 50 ratio of responsibility over time, although the improvement was more pronounced in the intervention group (13.3% vs. 10.4% in the control group).

Another secondary objective was to identify potential effect sizes that might be detected in an effectiveness trial and estimate an appropriate sample size for that trial. The results of the feasibility study provided us with some useful parameters to calculate a sample size calculation for the main trial. To take this in sequence, we first report the effect size results in the feasibility trial. In the feasibility study, approximately 3% of our sample reported unprotected sex at baseline (3.6% in the intervention group and 2.5% in the control group) and approximately 5% reported unprotected sex at follow-up 2 (5.4% in the intervention group and 5.6% in the control group). This amounted to a 50% increase in unprotected sex by follow-up 2 in the intervention group (3.6% at baseline rising to 5.4% at follow-up 2) compared with a more than doubling of unprotected sex by follow-up 2 in the control group (2.5% at baseline rising to 5.6% at follow-up 2).

We used this potential effect size to inform the sample size calculation for the main trial. The main trial will be powered to detect a 50% reduction in the incidence of unprotected sex (from an expected rate of 2.8% to 1.4%) by 15 years of age. A difference of 1.4% in unprotected sex has been shown to have a meaningful impact on pregnancy rates.^{18,122,124,149} The between-group difference in the incidence of unprotected sex of 1.3% (95% CI 0.5% to 2.2%) by 9 months in our feasibility trial demonstrates that such an effect size is plausible and is consistent with effect sizes seen in the literature.¹²² The study will take account of clustering. In the feasibility trial data the intraclass correlation coefficient (ICC) was 0.01. As pilot studies can provide imprecise estimates of ICCs,¹⁵⁰ we re-estimated using ICCs from three sources: (1) the Randomized Intervention of PuPil-Led sex Education (RIPPLE) cluster RCT; (2) data from the WHO Health Behaviour in School-aged Children Survey GB;¹²⁹ and (3) the Young Persons' Behaviour and Attitudes Survey 2011.⁹ The data from the WHO and Northern Ireland Statistics and Research Agency (NISRA) studies were combined. Both the RIPPLE and combined WHO and NISRA studies found an ICC of 0.004. In terms of our sample size calculation based on these data, first, based on the ICC of 0.01 (95% CI 0.01 to 0.04), and assuming 120 students per year group in school, and a 7% rate of attrition (based on the conservative attrition rate found in the feasibility study plus two additional schools), a trial involving 33 schools per group will provide 80% power at a 5% significance level. The power would rise to 93% if we used the alternative ICC of 0.004. Table 46 shows the sample size calculation based on the first ICC (0.01).

The final secondary objective was to identify the costs of delivering *If I Were Jack* and generate methods for assessing cost-effectiveness in a future trial. The mean cost of delivering *If I Were Jack* per pupil after adjusting for school cluster was £13.66. The economic cost was calculated to include teacher and school costs according to the principle of opportunity cost and using a microcosting approach taken from a public-sector decision-maker perspective. Preparation for a future cost-effectiveness decision model that incorporates theories of behaviour change was also undertaken. The structure of the model is illustrated in Figure 6. In the main trial, this framework will be populated with data from future primary research, policy documents and published literature (see further elaboration under progression rules below).

Criteria for progression to main trial

The following issues were considered when deciding whether or not to develop a protocol for a Phase III trial:

- The intervention is acceptable to schools (principals and RSE teachers), pupils and parents; can be feasibly implemented by teachers in schools in NI; and any indications of necessary further development do not exceed the PHA's contribution of £20,000. If there is a consensus among school teachers that the *If I Were Jack* intervention would be of little value to other schools or if fundamental logistical problems in its delivery become evident and cannot be rectified, we would not proceed to trial. The intervention is acceptable to schools as evidenced by positive evaluations from schools (principals and RSE teachers), pupils and parents. Participants suggested only minor amendments to the core intervention. However, participants did propose a significant refinement to the parental component of

TABLE 46 Sample size calculation for Phase III

Control	Intervention	Sample size per group	ICC (95% CI)	Cluster size	VIF	Multiply by VIF	Dropout rate	Inflated for dropouts	Divided by cluster size to give number of schools per group	Power
2.8%	1.4%	1646	0.01 (0.01 to 0.04)	120	2.19	3605	7% + two additional schools	3876	33	80%

VIF, Variance Inflation Factor.

the intervention because we did not attract sufficient numbers of parents to attend information and discussion sessions in the schools. Arising from process evaluation findings and consultation with trial steering group members, we propose to transform this element of the intervention from teacher-led information sessions that parents are required to attend into three short, highly engaging videos, which would be accessed electronically by parents. We anticipate that the cost of this refinement will be approximately £20,000 in production costs. However, separate funding has been obtained for this change from the HSC R&D.

Furthermore, as we now anticipate UK-wide effectiveness, we have completed a 'transferability study'^{144,145} of our intervention in Scotland, Wales and England with our collaborators. The transferability study was jointly funded through QUB and the Social and Public Health Sciences Unit of University of Glasgow and involved qualitative research on the suitability of the *If I Were Jack* intervention in three diverse schools and among key stakeholders in each of the other three countries of the UK. The results of this transferability study suggested that we should reshoot the interactive film for England and Wales using English actors, to enhance cultural sensitivity. In addition, in order to make both films identical and to take an opportunity to update computer-based technology and film, we would aim to reshoot the NI version for use in Scotland and Wales at the same time. In addition, the transferability study findings recommend that we make minor changes to the classroom materials to localise some of the references to services and increase compatibility with the respective RSE curricula of each of the nations where relevant. The cost of reshooting the film is estimated at £45,000. However, these costs would not be incurred if the main trial were to take place in NI only.

- Recruitment, participation and retention rates are likely to be adequate for a main trial. We would expect high rates of recruitment, participation and retention. However, if we do not recruit at least 25% of schools approached, we would not proceed to trial. Moreover, if we experience > 25% of parents withdrawing their children from the study or > 25% of pupils refusing to participate, we shall not proceed to trial. Finally, in relation to retention, if < 85% of pupils complete the primary outcome measure at follow-up, we would not proceed to trial.

Recruitment of schools was successful. A total of eight schools, six principals, two VPs, 40 teachers, and 831 pupils were recruited at baseline. The overall recruitment rate was 38%. The recruitment rate of RC schools was 30%.

The pupil recruitment rate was 80.9%. Parental withdrawal of consent accounted for 6.8% of loss ($n = 70$) and pupil opt-out for 3.1% ($n = 32$). Pupil absence or unavailability at baseline with absentee questionnaires and consent form not returned to the research team accounted for the remaining 9.1% ($n = 94$).

Retention of schools: all schools have remained in the trial at follow-up 2.

Retention of pupils in relation to primary outcome measure was 93% at follow-up 2.

- The potential effect sizes reported in the feasibility study indicate an achievable sample size (see sample size calculation of 66 schools reported above).
- The survey instruments can be feasibly delivered to time in the recruited schools and show acceptable reliability and validity. The instruments showed high acceptability. The majority of participants stated that they felt comfortable in answering most of the questions in the questionnaire (80%, $n = 608$). Paper-based surveys worked much better than electronic methods. In a future trial, we would hire two fieldworkers per classroom in order to more ably assist pupils with learning difficulties. We were able to collect data on all theoretically interesting mediating variables of knowledge, attitudes and self-efficacy to avoid a pregnancy and intentions to avoid a pregnancy. Overall, the reliability of the measures (scales) used to assess these variables was satisfactory. Cronbach's alpha was calculated as a measure of internal consistency/reliability for all scales. The Male Role Attitudes, Sexual Socialisation Peer scale, Sexual Self-Efficacy scale and TUPS all had high internal consistency (Cronbach's alpha in excess of 0.7); Family Connectedness, Comfort Communicating about Pregnancy, Comfort Communicating about Contraception, Sexual Socialisation Total and the Sexual Socialisation Parent scales had satisfactory internal consistency (Cronbach's alpha: 0.526–0.699).

We also tested a number of questions for use in a future health economic cost–benefit analysis, relating to contraceptive use, numbers of partners and self-reported records of STI diagnoses. The question on STI diagnoses worked poorly insofar as there was an especially high rate of non-response for this question (88.7% of missing data at follow-up 2). Nonetheless, we believe that this is mostly because of the low rates of STI diagnoses among young people under 16 years of age and hence a perceived irrelevance. We shall consult with our young people on the steering group and a planned young people’s advisory group on a future trial to ascertain how best to position the relevance of this question on a future questionnaire.

- An economic evaluation can be feasibly conducted as part of the main trial.
An economic evaluation can be feasibly conducted in a main trial as we have been able to achieve the groundwork for this in the feasibility trial. The aims of the economic component in the feasibility trial were to identify the costs of delivering *If I Were Jack* and to develop a framework for assessing cost-effectiveness in a future trial (see *Figure 6*). This was achieved by the following:
 1. The identification of the relevant resources used in the set up and delivery of *If I Were Jack* and their associated costs was completed using a microcosting approach, from a public-sector decision-maker perspective. Relevant costs were identified, measured and valued in monetary units using the 2013/14 price year, guided by a recognised practical guide to costing behavioural interventions.¹³² The mean cost per pupil for delivery of the intervention (including training of teachers) was calculated as £13.66.
 2. The identification of parameters for a future cost-effectiveness decision model that incorporates theories of behaviour change is illustrated in *Figure 6*.

The aim of the economic evaluation in the main trial, and as proposed now to be a UK-wide trial, as noted above, is to describe the costs and consequences of implementing *If I Were Jack* in schools across all countries of the UK so as to provide information to decision-makers on the implications of rolling out the intervention further. Initially, we plan to conduct an analysis of the opportunity costs of implementing *If I Were Jack* in trial schools in Scotland, England and Wales. This will include the duration of time taken up by *If I Were Jack* in school from the perspective of the teacher and the impact on time spent on other important curricula activities compared with time spent on standard RSE. The aim of this will be to provide a measure of the opportunity cost to schools of implementing *If I Were Jack* compared with current RSE in control schools. The structure of the evaluation will follow NICE guidance for evaluating public health interventions¹⁵¹ and recent guidance published by Edwards *et al.*¹⁵² on economic evaluations in public health. Costs will include the cost of implementing the intervention in schools including any training involved and the cost of current RSE in the control schools. We shall also collect information on health-care cost information in the intervention and control arms, including the costs of sexual health-related primary care attendances, costs of any STIs and cost of unintended pregnancies, although numbers of these are likely to be small. The cost of culturally adapting *If I Were Jack* to the different countries will also be reported, given that others may want to also adapt the intervention before rolling it out. Mean cost per pupil will be reported alongside consequences, including use of contraception, STIs and unintended pregnancies, which will be collected using questionnaires that are administered to pupils at baseline and follow-up. Costs will also be reported by country, given the different sexual health services provided and, hence, differential implications for health service costs by country.

Given that STIs and unintended pregnancies are likely to be rare but potentially high-impact events in this group, the long-term costs and consequences will be modelled as part of the decision model described above in point 2 and shown in *Figure 6*. In addition to collecting information as part of the trial, we shall look to systematic reviews in the literature of evidence of the impact of digital interventions on sexual health behaviour in this population group, for example the review recently undertaken and published by Bailey *et al.*⁵⁵ We shall review the literature for any gaps in evidence identified. We shall undertake one-way, two-way and probabilistic sensitivity analyses of the results. Cost-effectiveness acceptability curves and cost-effectiveness planes will be reported. The model will have a 20-year time horizon, and discounting of future costs and benefits will comply with NICE guidance for evaluating public health interventions.¹⁵¹

Summary findings relating to the evaluation of Relationship and Sexuality Education interventions in schools and future research

Thinking through implementation and evaluation from the outset of intervention design

In providing guidelines for the development and evaluation of complex interventions of this kind, the UK's MRC⁸⁹ recommend that high-quality evaluation is preceded by a systematic approach to intervention development. The iterative four-phase approach outlined in the MRC framework involves developmental work (referred to as 'Phase I' research), which includes identification of the evidence base, identification or development of theory relating to the phenomenon of interest and modelling of processes and outcomes to inform optimisation of the intervention prior to evaluation. However, in our view, although the MRC guidelines⁸⁹ suggest a very useful framework for conducting Phase I research, they provide little description of how this should proceed (relative to guidance provided on Phases II–IV). This effectively relegates the importance of this phase to brief summaries in evaluation research, despite growing consensus that the development of conceptually based, acceptable interventions is of vital importance before proceeding to trial. This is compounded by a dearth of published literature reporting the development of complex interventions more broadly but, also, specific developmental process in relation to RSE interventions are scant in the literature (for exceptions, see Carswell *et al.*,¹⁵³ Kirby *et al.*,⁹⁴ McCarthy *et al.*¹⁵⁴ and Wight and Abraham¹⁵⁵). The result is a paucity of models that might guide comparable research. In *Chapter 3* we report the intervention design process in detail to hopefully guide other researchers in the design phases of comparable interventions.

We also offer the following observation in relation to the MRC guidelines.⁸⁹ The MRC guidelines do not indicate the importance of considering implementation during Phase I, despite the fact that this might alert the researcher to factors that may impact on successful implementation. In discussing Phase IV, the guidelines indicate that 'successful implementation depends on changing behaviour – often of a wide range of people. This requires a scientific understanding of the behaviours that need to change, the factors maintaining current behaviour and barriers to and facilitators of change, and the expertise to develop strategies to achieve change based on this understanding'.⁸⁹ It seems likely many of these factors should be considered during the development phase, rather than post evaluation and this is the approach that we took during the study. The current study builds on the team's Knowledge Translation Award from the Economic and Social Research Council (RES-189–25–0300),¹⁵⁶ through which the intervention was initially developed and a 'translation study' offering insights into generating a culturally generalisable intervention across the UK.¹⁴⁴ It also follows foundational empirical groundwork generating understandings of adolescent males' attitudes towards and decision-making in relation to teenage pregnancy.^{1,90,93} A hallmark of this preparatory work has been meaningful consultation with all stakeholders, from pupils to senior policy-makers, ensuring that the *If I Were Jack* intervention can be sustainably implemented if proven to be effective. We would argue that an essential part of the design process involves thinking about and planning for all aspects of the research process that will follow – feasibility testing; evaluation; implementation, follow-up and monitoring.

The need for gender-sensitive interventions and gender analyses of Relationship and Sexuality Education interventions

The need for gender-sensitive interventions to address teenage pregnancy has been highlighted as a global health need by the WHO^{46,47} and recommended in systematic reviews of RSE education.^{19,48,49,157} Boys have been especially neglected in educational interventions in relation to teenage pregnancy.^{1,22,48,51–54} When they do receive RSE about pregnancy, it is often via programmes that are directed towards girls, although it is quite likely that males and females are affected differently by gender norms and values relating to pregnancy.² This is the first UK study of a gender-sensitive approach to prevent UTP and the first of its kind to specifically target teenage boys. Moreover, the study highlights the neglect of, and need for future research to report on, gender differences across the board in the evaluation of RSE interventions in order to better understand what works best for boys and girls.¹⁵⁷

The wider application of interactive video dramas in public health promotion and research

The appeal of the IVD as both a technological platform and a means of engaging young people in episodic thinking,^{158,159} which allows young people to think themselves into the future or into being a character, is perhaps noteworthy for future public health interventions. This original methodology was adapted from an earlier empirical project in which it was originally used as a tool for data collection.^{1,160} The *If I Were Jack* IVD has already inspired other researchers to adapt this methodology into a comparable schools-based intervention, entitled *Cycles*, to address adolescents and marijuana use in British Columbia.^{95,161} A further example is *If I Were Nick* – an internet-based smoking cessation intervention also directly inspired by *If I Were Jack* and collaboratively developed by Joan Bottorff and team with M Lohan as lead applicant.¹⁶² The intervention is hosted on the national website of *Quitnow Canada*.¹⁶³ Part of the appeal of incorporating IVDs is the opportunity to involve the target audience in foundational arts-based research to script realistic characters with whom and settings with which they can identify. The end product IVD then helps to contextualise health promotion messages in their own lives. This ethnographically informed drama production, combined with the interactive computer component used in the creation of the IVD, is the approach that we shall now pursue with incarcerated young men in relation to a programme designed to prevent unintended pregnancy and prepare incarcerated young men for future parenthood in co-operation with our prison partners at Hydebank Wood Secure College, Northern Ireland Prison Service.

The tension between creating culturally sensitive and universal interventions

Creating drama productions, and ultimately interventions, with which all young people can identify and/or which are appealing to all young people in any target group is unrealistic. Research teams have to think carefully about whether they want to balance their intervention towards a subgroup (e.g. black and minority ethnic groups) or go for a broader universal approach, which will inevitably exclude some subgroups. In our research, we made a decision early on in the design stage (in consultation with our educational stakeholders and through script readings with young people in drama groups) to go for the middle ground, representing the majority population in NI. The main protagonist was white, upper working-class with an urban Belfast accent and living with both parents. The likability of the main protagonist proved to be central to creating a universal appeal. In this feasibility trial we learned that the addition of an audio track may be of benefit to those with literacy difficulties. In the transferability study, we learned that there was acceptable cultural translation between our NI version of *If I Were Jack* and the Scottish population. Pupils here recognised that Jack was not Scottish, but crucially he was also not clearly identifiable as Protestant or Catholic and there was no substantial difficulties with comprehension. However, in England and Wales, cultural identification with a Northern Irish character and the comprehensibility of the accent were substantial barriers. Thus, we have made a decision to reshoot an English version for use in England and Wales. This was regarded as acceptable in both North and South Wales. It is also envisaged that the cast for this new English version will be more multiethnic. However, we shall have to consult closely with young people again when recasting, as all relationships depicted in the movie will have to be authentic and plausible.

Therefore, our simple conclusions in this regard are as follows. Consult with the target audience throughout. Recognise that producing universal interventions will involve uncomfortable compromises, in terms of not being able to address all audience needs. Luckily, however, films are culturally understood to be stories about some people, and it is inevitable that they will have greater appeal to some audiences.

Recruitment strategies and inclusion of faith based schools

In many ways, our recruitment experiences and our research with schools inquiring into the best ways to approach and recruit schools in this study reinforces some of the lessons already available in the literature (see *Table 18* for a summary). However, this study adds to the literature in the following ways. First, it suggests that the use of RSE training days for teachers is a very effective focal point for recruitment of schools for RSE research. In the UK countries, such as NI, Scotland and Wales, where there are national curricula for RSE and hence also statutory provision for training teachers, such training, we suggest, is a very efficient means of recruiting schools for trials of RSE interventions. Second, we would advocate for

audio-visual information sheets for pupils. Based on our interviews with teachers and pupils, we suggest that if these are made readily available to teachers, it will enhance the information and consent procedures for pupils. Third, and perhaps most importantly, we believe that this is the first RSE intervention trial to include faith-based schools in the UK. Given that > 50% of schools in NI are RC, this was especially important in NI. Nonetheless, as the UK becomes increasingly multicultural, with the corresponding growth of other faith-based schools, we suggest that future RSE research should also seek to include minority religious schools. We suggest that recruitment of these schools could be enhanced by inclusion of these types of schools in the design of interventions and in tailoring recruitment invitation letters to these schools to assuage anticipated concerns.

Involving parents through schools in relation to Relationship and Sexuality Education interventions

Although evidence suggests that schools are an important context for sex education,^{14,22,48} recent systematic reviews have also shown that programmes that reach beyond the classroom can enhance effectiveness.^{19,25,60} In particular, factors such as parental monitoring and supervision and familial communication have been associated with teenage sexual behaviours.^{61,62} Teenagers who can recall a parent communicating with them about sex are more likely to report delaying sexual debut and increased condom and contraceptive use.⁶³⁻⁶⁵ One element of the *If I Were Jack* theory of change involves increasing communication about UTP among parents and teens. First, the resource includes a homework task and materials to generate the communication from the child's perspective. Second, it includes teacher-facilitated information sessions with parents. As detailed in this report, both of these aspects, and especially the parent information sessions were the least successful in terms of intervention implementation. This caused us to rethink this component based on follow-up research with parents, consultation with our trial steering group and further explorations of the literature during this study. In relation to the homework task, we have decided to keep this component but to recognise that it will not be implemented universally and we shall continue to monitor this as part of the process evaluation in a full trial. In relation to the teacher-facilitated information sessions, we shall change this to the form of three short online animations/films for parents and guardians which will be texted/e-mailed to parents directly from the schools. The primary purpose of these three short films is to inform parents/guardians of the resource being used in the classroom and the homework activity, and to guide them with information about the importance of communicating with their child about teenage pregnancy and sexual health, and hints and tips for doing so. Recent studies^{68,69} demonstrate the importance of embracing such 'education entertainment' modalities as engaging adjuncts to school-based education. This refinement has been funded by the HSC R&D. It was completed in 2016 and will be tested in the main trial. The broader point that this raises, however, is how best to include parents in school-based RSE interventions for pupils and this is a question that we believe requires further research.

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Dr Rhonda Curran (Research Fellow at the School of Nursing and Midwifery, QUB) oversaw the compilation of this report, contributing to all of the chapters.

Mrs Cliona McDowell (Biostatistician at NICTU) conducted the statistical analysis for the quantitative results and contributed to the quantitative results chapter.

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Dr Lisa McDaid (Programme Leader – Social Relationships and Health Improvement, MRC/Chief Scientist Office Social & Public Health Sciences Unit) advised on study design and execution and contributed to the literature review.

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Dr Peter O'Halloran (Lecturer, at the School of Nursing and Midwifery, QUB) contributed to the design of the intervention, the design of the feasibility study and the organisation of PPI.

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The intervention described in the above article is based on the *If I Were Jack* methodology of interactive IVDs and was developed in relation to smoking cessation.

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Data sharing statement

All data can be obtained from the corresponding author.

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Appendix 1 Participant letters of invitation, information leaflets and consent forms

PARENT DOCUMENTS

Letter to parents/guardians - questionnaire development

Information sheet for parents/guardians - questionnaire development

Withdrawal of consent form for parents/guardians - questionnaire development

Letter to parents/guardians - feasibility study

Information sheet for parents/guardians - feasibility study

Withdrawal of consent form for parents/guardians - feasibility study

Information and discussion session letter template for parents/guardians

Information sheet for parents/guardians - focus group participation by intervention group

Consent form for parents/guardians - focus group participation by intervention group



Dr Maria Lohan

Senior Lecturer

[REDACTED]
[REDACTED]
[REDACTED]

[DATE]

RE: Research study - Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

Dear Parent/Guardian,

I am writing to invite your child/children to participate in a research study. The overall aim of the research is to examine the acceptability and practicality of using and evaluating a unique and scientifically informed educational resource on the topic of teenage men and unintended pregnancy in post-primary schools in Northern Ireland. The aim of the educational resource is to increase boys' as well as girls' intention to avoid an unintended teenage pregnancy.

The resource was developed by a research team at Queen's University Belfast in collaboration with key stakeholders in Northern Ireland which include the Department of Health, Social Services and Public Safety Northern Ireland, the Public Health Agency Northern Ireland, the and Council for Curriculum Education and Assessment Northern Ireland (CCEA). The research is funded by the UK National Institute for Health Research.

A preliminary aim of the study is to develop a short questionnaire which will enable us to gauge the impact of the resource on a range of outcomes including young people's knowledge, communication skills, intentions to avoid unplanned teenage pregnancy, and

sexual risk-taking behaviour. *It is for this preliminary part of the study that we request your child's participation.*

We would like to invite approximately 50-60 male and female Year 11 pupils to complete an online version the questionnaire during one Relationship and Sexuality Education (RSE) lesson in May 2014. Additionally, we are hoping to talk to a smaller group of these pupils (approximately 10) in a focus group discussions with a trained researcher regarding the acceptability of the questions included in the questionnaire. The questionnaire takes around 25 minutes to complete and the focus group discussion an additional 30 minutes.

We would value your child's participation in this research, as their contribution would inform a process of generating knowledge about effective sexual health resources for young people in Northern Ireland. Participation is, however, entirely voluntary and your child is under no obligation to take part. The principal of your child's/children's school and their RSE teacher have been informed about the research and have agreed to allow pupils to participate.

I have enclosed an information sheet which provides a brief overview of the research. Please read this information carefully. If you decide after reading the information sheet that you would prefer your child not to take part in this research, then you can indicate this by signing the attached 'opt-out' form and returning it to us in the stamped addressed envelope provided. If you are happy for your child to take part you need take no further action.

Yours sincerely,



Dr Maria Lohan

Signed: [RSE Teacher] _____



Queen's University
Belfast

Information about the Research (Questionnaire Development Study) Parents/Guardians

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

We would like to invite your child to take part in a research study. Before you decide whether you wish your child to take part, you should understand why the research is being done, and what it would involve for your child. Please take time to read the following information carefully.

Who is organising and funding the research?

The research is funded by the UK National Institute for Health Research Public Health Research Programme, an organisation which funds research to evaluate interventions intended to improve the health of the public and reduce inequalities in health. The research will be conducted by a team of researchers from Queen's University Belfast. The research project starts in May 2014, and is due to be completed in April 2016.

What is the purpose of the study?

Teenage girls who have an unplanned pregnancy face serious emotional and practical problems as well as risks to their health. Young men's health and wellbeing can also be affected by teenage pregnancy and young men have an important role to play in preventing unintended pregnancy. The overall aim of this study is to test the acceptability and practicality of introducing a resource which is designed to help teenage boys as well as girls avoid an unintended pregnancy. A preliminary aim of the study is to develop a brief questionnaire which will enable us to gauge the impact of the resource on a range of outcomes including young people's knowledge, communication skills, intentions to avoid unplanned teenage pregnancy, and sexual risk-taking behaviour.

The resource is designed for use at Key Stage 4 within the *Personal Development* strand of the *Learning for Life and Work* curriculum and has been developed in close consultation with

health and education experts (including the Public Health Agency Northern Ireland and the Council for Curriculum Education and Assessment Northern Ireland [CCEA]) as well as teachers, parents and pupils. **We wish to emphasise and reassure you that the content of the resource and questionnaire being used in the research do not contain any material that is sexually explicit.** The focus is on educating young people about unintended teenage pregnancy with a particular emphasis on the roles and responsibilities of teenage men in relation to this.

Why has my child been invited?

We are asking 50-60 Year 11 pupils in your child's school to take part in the questionnaire development phase of the research. Your child has been invited because he/she is part of this group.

Does my child have to take part?

No. It is up to you and your child to decide. In the first instance, if you decide after having read this information sheet that you would prefer your child not to take part in this research, then you can indicate this by signing the attached 'opt-out' form and returning it to us in the stamped addressed envelope provided. We will then ensure that your child **is not** included in the research by informing his/her RSE teacher to withdraw him/her from participation in the study. Suitable alternative supervision will be provided for your child while the study is taking place. If, however, you are happy for your child to take part in the research then we will also describe the study and go through a similar information sheet (which we will then give to your child) with him/her. We will then ask your child to sign a consent form to show that he/she has agreed to take part. We will give your child a copy of the consent form to keep. He/she can decide not to take part and he does not have to give a reason for saying no.

What if my child decides to withdraw from the study?

Your child is free to withdraw at any time, without giving a reason. If your child does withdraw we will not use the data we have collected from him/her.

What will my child be asked to do if he/she takes part?

There are two parts in the research. We would like everyone to participate in Part One and a smaller number of pupils at Part Two.

Part one: If you agree to your child taking part, at stage one he/she will be asked to fill in a questionnaire about: knowledge of ways to avoid teenage pregnancy and the possible negative consequences of unintended teenage pregnancy; sexual experience; use of contraception; diagnosis of sexually transmitted infections; comfort communicating about sexual relationships and teenage pregnancy with parents, partners and peers; and the strength of their intention to avoid pregnancy during adolescence.

This should take no more than 25 minutes and will happen on school premises. Part two will take place directly afterwards.

Part two: A random selection of around 10 pupils will be chosen to participate in Part two which is a focus group discussion. If your child is selected to take part in the focus group, he/she will be again asked to give his/her consent to participate and offered the chance to withdraw without giving a reason. This part of the research will mean two groups of around 5 pupils who have completed the questionnaire meeting with a researcher for 30 minutes. The researcher will ask them to give their views on the acceptability of the questions included in the questionnaire. The conversation will be tape recorded so that we can write out the discussion and see where the pupils agree and disagree. All identifying features of your child and his/her school will be removed from the written version.

Your child may offer to take part at part one only or at both part one and part two.

What if there is a problem?

If you or your child are unhappy with anything that happens during the study you can talk to teachers or the researchers. If an issue is brought to the attention of the researchers, we will deal with it immediately. If pupils show any signs of visible distress, we will inform the school counsellor. Again, pupils can withdraw from the study at any time, without giving a reason. They can also make a formal complaint if they wish (details of how to do this are set out at the end of this document).

Will my child's taking part in the study be kept confidential?

All information gathered during the course of the research will be kept strictly confidential unless child protection, illegal or professional misconduct issues arise. If anything is disclosed during the course of the research that suggests that an individual is involved in or at risk of harmful or criminal activity the researcher will be obliged to pass this information on to the relevant authorities.

Only the researchers will have access to the data. We will follow ethical and legal guidelines and keep all information privately and securely. Your child will not be asked to put his/her name or the name of the school on the questionnaire. We will store the questionnaires and all other paper data in a locked filing cabinet in a secure building at Queen's University Belfast. Names of individuals or schools stored on a computer will be password protected and deleted at the end of the study. Paper data will be destroyed securely five years after the study ends. We will listen to the tapes of the focus group interviews and write down what is said. We will not write down names or anything else that would identify any individual.

At the end of the study, all data resulting from the research (including the tapes and transcripts) will be stored for a minimum of 5 years and a maximum of 10 years in Queen's University Belfast. All data will be archived by year 10 in The UK Data Archive (UKDA) located in the University of Essex. This is a centre that specialises in keeping data securely so that other researchers can apply for ethical permission to use it in their own research.

Will I be asked to participate in any part of the study?

No. This part of the study involves pupils only.

What will happen to the results of the research study?

The results of the study will be published in research reports and in scientific journals. We will not publish anything that could be used to identify you, your child or the school. We will send copies of reports and journal articles to your child's school so that you and he/she can read them if you want to.

Who has reviewed the study?

All research is looked at by independent group of people, called a Research Ethics Committee, to protect all participants' safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Research Ethics Committee of the School of Nursing and Midwifery, Queen's University Belfast.

Further information and contact details

If you would like further information about the research, please contact Dr Áine Aventin or Dr Maria Lohan.

Dr Áine Aventin
Research Fellow



Dr Maria Lohan
Senior Lecturer



What if I want to make a complaint?

If you and/or your child are unhappy with any part of the study and do not wish to approach the research team, please contact Dr Oliver Perra, Chair of the Research Ethics Committee of the School of Nursing and Midwifery, Queen's University Belfast.

Dr Oliver Perra
School of Nursing and Midwifery





Opt-Out Form

(Questionnaire Development Study)

Parents/Guardians

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

	Please circle answer
1. I have read and understood the information sheet dated (version).	Yes / No
2. I understand what the research is about.	Yes / No
3. I DO NOT give my permission for my child to take part in the study.	Yes / No

You do not need to give a reason for withdrawing your child from the study but if you wish to give a reason please write below.

Please write and sign your name and insert today's date below.

Your Name

Date

Signature

Your

Child/Children's

Name



Dr Maria Lohan

Senior Lecturer



[DATE]

RE: Research study - Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

Dear Parent/Guardian,

I am writing to invite your child to participate in a research study. The overall aim of the research is to examine the acceptability and practicality of using and evaluating a unique and scientifically informed educational resource on the topic of teenage men and unintended pregnancy in post-primary schools in Northern Ireland. The aim of the educational resource is to increase boys' as well as girls' intention to avoid an unintended teenage pregnancy.

The resource was developed by a research team at Queen's University Belfast in collaboration with key stakeholders in Northern Ireland which include the Department of Health, Social Services and Public Safety Northern Ireland, the Public Health Agency Northern Ireland, the Council for Curriculum Education and Assessment Northern Ireland (CCEA) as well as teachers, parents and pupils. It is designed to fit within the Personal Development strand of the Learning for Life and Work curriculum and to be used in Year 11.

We would value your child's participation in this research, as your contribution would inform a process of generating knowledge about effective sexual health resources for young

people in Northern Ireland. I have enclosed an information sheet which provides a brief overview of the research. Please read this information carefully. If you decide after reading the information sheet that you would prefer your child not to take part in this research, then you can indicate this by signing the attached 'opt-out' form and returning it to us in the stamped addressed envelope provided. If you are happy for your child to take part you need take no further action.

Yours sincerely,



Dr Maria Lohan

Signed:

[RSE

Teacher]



Information about the Research Parents/Guardians

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

We would like to invite your child to take part in a research study. Before you decide whether you wish your child to take part, you should understand why the research is being done, and what it would involve for your child. Please take time to read the following information carefully.

Who is organising and funding the research?

The research is funded by the UK National Institute for Health Research Public Health Research Programme (NIHR PHR). The NIHR PHR funds research to evaluate non-NHS interventions intended to improve the health of the public and reduce inequalities in health. The research will be conducted by a team of researchers from Queen's University Belfast. The research project starts in May 2014, and is due to be completed in April 2016.

What is the purpose of the study?

Teenage women who have an unplanned pregnancy face serious emotional and practical problems as well as risks to their health. Young men's health and wellbeing can also be affected by teenage pregnancy and young men have an important role to play in preventing unintended pregnancy. The overall aim of this study is to test the acceptability and practicality of introducing an educational resource which is designed to help teenage boys as well as girls avoid an unintended pregnancy.

What is the educational resource?

The resource is designed for use at Key Stage 4 within the Personal Development strand of the *Learning for Life and Work* curriculum and has been developed in close consultation with health and education experts (including the Public Health Agency Northern Ireland and the Council for Curriculum Education and Assessment Northern Ireland [CCEA]) as well as teachers, parents/guardians and pupils. It includes the following components:

- i. An interactive film about a 16-year old boy who has just found out that his girlfriend is unexpectedly pregnant;

- ii. Training and classroom materials for teachers containing four detailed lesson plans with specific classroom-based and homework activities which include group discussions, role-plays, worksheets, and a parent-pupil exercise;
- iii. 60-minute information and discussion session for parents/guardians delivered by RSE teachers; and
- iv. Detailed information brochures and factsheets about the resource and unintended teenage pregnancy in general for schools, teachers, pupils and parents/guardians.

We wish to emphasise and reassure you that the content of the resource and questionnaires being used in the research do not contain any material that is sexually explicit. The focus is on educating teenagers about unintended teenage pregnancy with a particular emphasis on the roles and responsibilities of teenage men in relation to this.

Why has my child been invited?

We are asking all Year 11 pupils in seven post-primary schools in Northern Ireland to take part in the research. Your child has been invited because he/she is part of this group.

Does my child have to take part?

No. It is up to you and your child to decide. In the first instance, if you decide after having read this information sheet that you would prefer your child not to take part in this research, then you can indicate this by signing the attached 'opt-out' form and returning it to us in the stamped addressed envelope provided. We will then ensure that your child **is not** included in the research by informing his/her RSE teacher to withdraw him/her from participation in the study. Suitable alternative supervision will be provided for your child while the study is taking place. If, however, you are happy for your child to take part in the research then we will also describe the study and go through a similar information sheet (which we will then give to your child) with him/her. We will then ask your child to sign a consent form to show that he/she has agreed to take part. We will give your child a copy of the consent form to keep. He/she can decide not to take part and he does not have to give a reason for saying no.

What if my child decides to withdraw from the study?

Your child is free to withdraw at any time, without giving a reason. If your child does withdraw we will not use the data we have collected from him/her.

What will my child be asked to do if he/she takes part?

Of the 7 schools who agree to participate, 4 will be randomly assigned to the 'intervention group' and 3 will be randomly assigned to the 'comparison group'. Teachers and pupils in the intervention group schools will be asked to use the educational resource during four weekly RSE lessons and those in the comparison group will continue with normal RSE practice. At the end of the study we will compare the results of questionnaires completed by pupils in the two groups to see if it is possible to measure the impact of the educational resource on pupils' knowledge, communication skills, intentions to avoid teenage pregnancy and sexual risk-taking behaviour.

All Year 11 pupils in the 7 participating schools will complete the same questionnaire on three occasions over a 12-month period (at the beginning of the research and 5 and 9 months later). The questionnaire will contain questions about your child's knowledge of teenage pregnancy; sexual experience; use of contraception; diagnosis of sexually transmitted infections; and comfort communicating about sexual relationships and teenage pregnancy with parents/guardians, partners and peers.

Pupils in *intervention group schools* will receive the educational resource during four consecutive RSE lessons. Approximately 5 pupils from each Year 11 class will be asked to take part in a 30 minute focus group discussion with a researcher regarding the acceptability and feasibility of the resource and participation in the research.

In addition to completing the questionnaire on three occasions over a 12-month period, a sample of pupils in *comparison group schools* (two groups of 5) will be asked to take part in a 30 minute focus group discussion with a researcher regarding the acceptability of the questionnaire.

Will I be asked to take part?

All parents/guardians of pupils in *intervention group schools* will be invited to participate in a 60-minute parents/guardians' information and discussion session at the school facilitated by an RSE teacher. The session will include information about the resource and discussion around how best to talk to teenagers about avoiding unintended pregnancy. A sample of these parents/guardians (approximately 5 -8) will also be invited to take part in a group discussion with the researcher regarding the acceptability and feasibility of the resource and the discussion session. Parents/guardians will also be asked to participate in a short homework exercise with their child as part of the intervention in which they answer their child's questions about their views on teenage pregnancy. Following this homework exercise they will be sent a link to a short online survey regarding their experiences of this.

Parents/guardians of pupils in *comparison group schools* will not be invited to participate in the research.

The timetable below summarises what pupils and parents in intervention and comparison group schools would be asked to do during the study.

Please note: in line with best practice recommendations, schools will not be randomly assigned to intervention or comparison groups until after pupils have completed the questionnaire for the first time.

Research Timetable

DATE	INTERVENTION SCHOOLS	COMPARISON SCHOOLS
Sept – Oct 2014	Parents/guardians sent information about the research	Parents/guardians sent information about the research
Dec 2014	Pupils consent to participate & complete questionnaire during 1 RSE lesson School notified of allocation to intervention group	Pupils consent to participate & complete questionnaire during 1 RSE lesson School notified of allocation to comparison group
Jan – Feb 2015	Pupils receive resource over 4 consecutive RSE lessons Parents/guardians' attend 60-minute information and discussion session at school Researcher observes one RSE lesson and one parents/guardians' information session in each school	
Mar - 2015	Focus groups pupils, focus group parents/guardians (<i>acceptability and feasibility of the resource</i>)	
June 2015	Pupils complete questionnaire during 1 RSE lesson	Pupils complete questionnaire during 1 RSE lesson

Sept - Oct 2015	Pupils complete questionnaire during 1 RSE lesson	Pupils complete questionnaire during 1 RSE lesson Focus groups with pupils (<i>acceptability of questionnaire</i>)
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What are the benefits of taking part?

The research would provide you and your child with an opportunity to be involved in the evaluation of an innovative relationship and sexuality education resource that is designed to decrease unintended teenage pregnancy. The findings will be widely shared and should help to inform future policy and practice regarding pregnancy education for young people in Northern Ireland.

What if there is a problem?

If you or your child are unhappy with anything that happens during the study you can talk to the teacher and/or the researchers. If an issue is brought to the attention of the researchers, we will deal with it immediately. If pupils show any signs of visible distress, we will inform the school counsellor. Participants can also make a formal complaint if they wish (details of how to do this are set out at the end of this document).

Will our taking part in the study be kept confidential?

All information gathered during the course of the research will be kept strictly confidential unless child protection, illegal or professional misconduct issues arise. If anything is disclosed during the course of the research that suggests that an individual is involved in or at risk of harmful or criminal activity the researcher will be obliged to pass this information on to the relevant authorities.

Only the researchers will have access to the data. We will follow ethical and legal guidelines and keep all information privately and securely. Your child will not be asked to put their name or the name of the school on the questionnaires. We will store the questionnaires and all other paper data in a locked filing cabinet in a secure building at Queen's University Belfast. Names of individuals or schools stored on a computer will be password protected and deleted at the end of the study. Paper data will be destroyed securely five years after the study ends. We will listen to the tapes of the focus group interviews and write down what is said. We will not write down names or anything else that would identify any individual or school.

At the end of the study, all data resulting from the research (including the tapes and transcripts) will be stored for a minimum of 5 years and a maximum of 10 years in

Queen's University Belfast. All data will be archived by year 10 in The UK Data Archive (UKDA) located in the University of Essex. This is a centre that specialises in keeping data securely so that other researchers can apply for ethical permission to use it in their own research.

What will happen to the results of the research study?

The results of the study will be published in research reports and in scientific journals. We will not publish anything that could be used to identify you, your pupils or the school. We will send copies of reports and journal articles to your school so that participants can read them if they want to.

Who has reviewed the study?

All research is looked at by independent group of people, called a Research Ethics Committee, to protect all participants' safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Research Ethics Committee of the School of Nursing and Midwifery, Queen's University Belfast.

Further information and contact details

If you would like further information about the research, please contact Dr Áine Aventin or Dr Maria Lohan.

Dr Áine Aventin
Research Fellow



Dr Maria Lohan
Senior Lecturer



What if I want to make a complaint?

If you and/or your staff or pupils are unhappy with any part of the study and do not wish to approach the research team, please contact:

Dr Oliver Perra,

Chair of the Research Ethics Committee,

**Opt-Out Form****Parents/Guardians**

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

	Please circle answer
1. I have read and understood the information sheet dated (version).	Yes / No
2. I understand what the research is about.	Yes / No
3. I DO NOT give my permission for my child to take part in the study.	Yes / No

You do not need to give a reason for withdrawing your child from the study but if you wish to give a reason please write below.

Please write and sign your name and insert today's date below.

Your Name

Date

Signature

Your

Child/Children's

Name

INFORMATION & DISCUSSION SESSION LETTER TEMPLATE FOR PARENTS

Dear Parent/Guardian,

We are writing to inform you about an educational resource that your child will be using during four upcoming RSE lessons. The resource, named 'If I were Jack...' focuses on the topic of teenage pregnancy from the perspective of young men although it is suitable for use by young men and young woman. The aim of the resource is to increase young people's intention to avoid an unintended pregnancy.

The resource is based around an interactive video drama (IVD), which consists of a short film telling the story of a teenager, Jack, who has just found out that his girlfriend is unexpectedly pregnant. The young person watches the film (ideally at a computer on their own) and as the story unfolds questions appear on the screen which they must answer before continuing. The resource encourages the young person to put themselves in Jack's shoes and to consider the impact that an unintended teenage pregnancy might have on their own life.

The IVD is accompanied by other classroom-based activities (such as group discussion, role play and individual worksheets), which encourage students to think about and plan to avoid unintended pregnancy. One of the activities includes a homework exercise in which pupils are asked to encourage a parent or guardian to watch the IVD and then answer a number of questions on issues raised in the film. The aim is to provide parents/guardians and teenagers an opportunity to communicate about sex, relationships and pregnancy. A copy of the survey is enclosed for your information. Please be aware that the homework exercise will not be collected by the teacher and pupils will be advised to keep your responses confidential.

The resource has been developed to fit within the RSE curriculum by a team of researchers at Queen's University Belfast in consultation with key stakeholder partners including health and education experts from the Department of Health, Social Services & Public Safety (DHSSPS), the Public Health Agency (PHA) and the Council for the Curriculum Education and Assessment (CCEA), as well as teacher

trainers, teachers, parents and young people. More information on the resource is provided in the enclosed If I Were Jack Factsheet.

If you have any concerns about your child using this resource please do not hesitate to contact me.

Yours sincerely,

[RSE Teacher Signature]



Information about the Research

FOCUS GROUPS

Parents/Guardians Intervention Group

You have already been a participant in the first part of this research by attending a parents/guardians' information and discussion session about the *If I Were Jack* resource and unintended teenage pregnancy. Thank you for your time and cooperation in this stage of the research.

You are now being invited to take part in the next stage of the research which involves participating in a focus group discussion. You will be asked to give your consent to participate and offered the chance to withdraw without giving a reason.

This part of the research will mean a group of parents/guardians meeting with a researcher for a maximum of 60 minutes. The researcher will ask the participants to discuss their experiences of the resource and taking part in the research. The conversation will be tape recorded so that at a later stage we can write out the discussion and see where parents agree and disagree. All identifying features of you and your school will be removed from the written version.

A reminder of the purpose of the study

Teenage girls who have an unplanned pregnancy face emotional and practical problems as well as risks to their health. Teenage boys' health and wellbeing can also be affected by teenage pregnancy and young men have an important role to play in preventing unintended pregnancy. The overall aim of this study is to test an educational resource based around an interactive film that is designed to help young people (boys and girls) avoid an unintended pregnancy.

Do I have to take part?

No. It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. We will give you a copy of the consent form to keep. You can decide not to take part and you do not have to give a reason for saying no. You are free to withdraw at any time, without giving a reason. If you do withdraw we will not use the information we have collected from you.

Will we tell anyone what you say or do during the research?

No. We will not use the names of individuals or schools when they write about the research. However, if you say anything during the research that makes the researcher think that you or

another person is at risk of harm the researcher will have to talk to the school principal about it.

What if something upsets you?

We hope that you will enjoy taking part in the study. However, if you feel in any way upset as a result of taking part or unhappy with anything that happens during the study you can talk to the researchers.

What will happen to the results of the research study?

The results of the study will be published in research reports and in scientific journals. We will not publish anything that could be used to identify you or your school. We will send copies of reports and journal articles to your child's school so that you can read them if you want to.

Further information and contact details

If you would like further information about the research, please contact Dr Áine Aventin or Dr Maria Lohan.

Dr Áine Aventin
Research Fellow

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Dr Maria Lohan
Senior Lecturer

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

What if I want to make a complaint?

If you are unhappy with any part of the study and do not wish to approach the research team, please contact: Dr Oliver Perra; School of Nursing and Midwifery; Queen's University Belfast; 97 Lisburn Road; Belfast BT9 7BL



Consent Form

(Focus Group)

Parents/Guardians

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

	Please circle answer
1. I have read and understood the information sheet dated (version).	Yes / No
2. I understand what the research is about.	Yes / No
3. I understand that my participation is entirely voluntary and that I am free to withdraw at any time without giving a reason.	Yes / No
4. I understand that relevant sections of data collected during the study may be looked at by responsible individuals from the research team, and that information gathered will be stored securely, coded anonymously and presented in aggregate form so that no individual or organisation is recognisable.	Yes / No
5. I understand that all information gathered during the course of the research will be kept strictly confidential unless child protection, illegal or professional misconduct issues arise. If anything is disclosed during the course of the research that suggests that an individual is involved in or at risk of harmful or criminal activity the researcher will be obliged to pass this information on to the relevant authorities.	Yes / No
6. I agree to take part in the study according to the conditions outlined in the information sheet.	Yes / No

Please write and sign your name and insert today's date below.

Your Name**Signature****Date**

Keep one copy of this form for yourself and return the other one to the researcher. Thank you!

PUPIL DOCUMENTS

Information sheet for pupils - questionnaire development

Consent form for pupils - questionnaire development

Information sheet for pupils - focus group participation - questionnaire development

Consent form for pupils - focus group participation - questionnaire development

Information sheet for pupils - feasibility study

Consent form for pupils - feasibility study

Information sheet for pupils - focus group participation by intervention group – feasibility study

Consent form for pupils - focus group participation by intervention group – feasibility study

Information sheet for pupils - focus group participation by comparison group – feasibility study

Consent form for pupils - focus group participation by comparison group – feasibility study



Information about the Research (Questionnaire Development Study) Pupils

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

Hi, my name is Maria and I work along with Áine and others at Queen's University Belfast. We would like to invite you to take part in a research study. Before you decide whether you wish to take part, you need to understand why the research is being done, and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish.

What is the purpose of the study?

Teenage girls who have an unplanned pregnancy face emotional and practical problems as well as risks to their health. Teenage boys' health and wellbeing can also be affected by teenage pregnancy and young men have an important role to play in preventing unintended pregnancy. The overall aim of this study is to test a resource based around an interactive film that is designed to help young people (boys and girls) avoid an unintended pregnancy. In order to test whether the resource is useful for young people, we need to develop a questionnaire which can measure their knowledge, communication skills, intentions to avoid unplanned teenage pregnancy, and sexual risk-taking behaviour before and after using the resource. We would like you to help us develop the questionnaire.

Why have I been invited?

We are asking 50-60 Year 11 pupils in your school to take part in the research. You have been invited because you are part of this group.

Do I have to take part?

No. It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. We will give you a copy of the consent form to keep. You can decide not to take part and you do not have to give a reason for saying no. You are free to withdraw at any time, without giving a reason. If you do withdraw we will not use the information we have collected from you.

What about my parents/guardians?

We will send an information sheet to your parents or guardians so that, if you wish, you can discuss the study with them and decide together whether you would like to take part. Your parents have also been given the right to withdraw you from the study by signing an 'opt out' form and returning it to the researcher.

What will I be asked to do if I take part?

There are two parts in the research. We would like everyone to participate in Part one and a smaller number of people at Part two.

Part one: If you decide to take part in part one, you will be asked to fill in a questionnaire containing questions about your knowledge of teenage pregnancy; sexual experience; use of contraception; diagnosis of sexually transmitted infections; and comfort communicating about sexual relationships and teenage pregnancy with parents, partners and peers. This should take no more than 25 minutes and will happen during an RSE lesson. Part two will take place directly afterwards.

Part two: A random selection of around 10 pupils will be chosen to participate in Part two which is a focus group discussion. If you are selected to take part in the focus group, you will be again asked to give your consent to participate and offered the chance to withdraw without giving a reason. This part of the research will mean two groups of around 5 pupils who have completed the questionnaire meeting with a researcher for 30 minutes. The researcher will ask you to give your views on the acceptability of the questions included in the questionnaire. The conversation will be tape recorded so that we can write out the discussion and see where the pupils agree and disagree. All identifying features of you and our school will be removed from the written version. You may take part at part one only or at both part one and part two.

Will we tell anyone what you say or do during the research?

No. You will not be asked to put your name on the questionnaire and the researchers will not use the names of individuals or schools when they write about the research. However, if you say anything during the research that makes the researcher think that you or another young person is at risk of harm the researcher will have to talk to the school counsellor and/or principal about it.

What if something upsets you?

We hope that you will enjoy taking part in the study. However, if you feel in any way upset as a result of taking part or unhappy with anything that happens during the study you can talk to your parents/guardians, your teachers or to the researchers.

What will happen to the results of the research study?

The results of the study will be published in research reports and in scientific journals. We will not publish anything that could be used to identify you or your school. We will send copies of reports and journal articles to your school so that you can read them if you want to.

Further information and contact details

If you would like further information about the research, please contact Dr Áine Aventin or Dr Maria Lohan.

Dr Áine Aventin
Research Fellow

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Dr Maria Lohan
Senior Lecturer

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

What if I want to make a complaint?

If you are unhappy with any part of the study and do not wish to approach the research team, please contact Dr Oliver Perra, Chair of the Research Ethics Committee of the School of Nursing and Midwifery, Queen's University Belfast.

Dr Oliver Perra

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]



Consent Form
(Questionnaire Development Study)
Pupils

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

	Please circle answer
1. Have you read the information sheet?	Yes / No
2. Have you had a chance to think about the information and ask questions?	Yes / No
3. Do you understand what the research is about?	Yes / No
4. Do you understand that it's OK to stop taking part at any time without giving a reason?	Yes / No
5. Do you understand that any information which suggests that a young person is at risk of harm will have to be passed on to the school counsellor and/or school principal?	Yes / No
6. Are you happy to fill in a questionnaire during one RSE lesson?	Yes / No
7. Are you happy to take part in a 30-minute group discussion with a researcher and other pupils after you have filled in the questionnaire?	Yes / No
8. Are you happy for the group discussion to be tape recorded?	Yes / No
9. Do you agree to take part in this study?	Yes / No

Please write and sign your name or initials and today's date below.

Signature or Initials

Date

Keep one copy of this form for yourself and give the other one to the researcher. Thank you very much!!



Information about the Research

FOCUS GROUPS

Pupils

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland (Questionnaire Development Study)

You have already been a participant in the first part of this research by completing a questionnaire. Thank you for your time and cooperation in this stage of the research.

You have now been randomly selected to take part in the next stage of the research which involves participating in a focus group discussion. You will be again asked to give your consent to participate and offered the chance to withdraw without giving a reason.

This part of the research will mean a group of up to 10 pupils meeting with a researcher for 30 minutes. The researcher will ask the participants to discuss the questions included in the questionnaire. The conversation will be tape recorded so that at a later stage we can write out the discussion and see where pupils agree and disagree. All identifying features of you and your school will be removed from the written version.

You were provided with an Information Sheet before completing the questionnaire that provided information about the study, and that Information Sheet was yours to take away with you. We will also remind you now what the study is about, and emphasise that this Information Sheet is also yours to take away. We will also remind you about other important issues that were raised in the first Information Sheet that we provided.

A reminder of the purpose of the study

Teenage girls who have an unplanned pregnancy face emotional and practical problems as well as risks to their health. Teenage boys' health and wellbeing can also be affected by teenage pregnancy and young men have an important role to play in preventing unintended pregnancy. The overall aim of this study is to test a resource based around an interactive film that is designed to help young people (boys and girls) avoid an unintended pregnancy. In order to test whether the resource is useful for young people, we need to develop a questionnaire which can measure their knowledge, communication skills, intentions to avoid

unplanned teenage pregnancy, and sexual risk-taking behaviour before and after using the resource. We would like you to help us develop the questionnaire.

Do I have to take part?

No. It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. We will give you a copy of the consent form to keep. You can decide not to take part and you do not have to give a reason for saying no. You are free to withdraw at any time, without giving a reason. If you do withdraw we will not use the information we have collected from you.

Will we tell anyone what you say or do during the research?

No. You will not be asked to put your name on the questionnaire and the researchers will not use the names of individuals or schools when they write about the research. However, if you say anything during the research that makes the researcher think that you or another young person is at risk of harm the researcher will have to talk to the school counsellor and/or principal about it.

What if something upsets you?

We hope that you will enjoy taking part in the study. However, if you feel in any way upset as a result of taking part or unhappy with anything that happens during the study you can talk to your parents/guardians, your teachers or to the researchers.

What will happen to the results of the research study?

The results of the study will be published in research reports and in scientific journals. We will not publish anything that could be used to identify you or your school. We will send copies of reports and journal articles to your school so that you can read them if you want to.

Further information and contact details

If you would like further information about the research, please contact Dr Áine Aventin or Dr Maria Lohan.

Dr Áine Aventin
Research Fellow

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Dr Maria Lohan
Senior Lecturer

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

What if I want to make a complaint?

If you are unhappy with any part of the study and do not wish to approach the research team, please contact Dr Oliver Perra, Chair of the Research Ethics Committee of the School of Nursing and Midwifery, Queen's University Belfast.

Dr Oliver Perra

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]



Consent Form

FOCUS GROUPS

Pupils

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland (Questionnaire Development Study)

	Please circle answer
1. Have you read the information sheet?	Yes / No
2. Have you had a chance to think about the information and ask questions?	Yes / No
3. Do you understand what the research is about?	Yes / No
4. Do you understand that it's OK to stop taking part at any time without giving a reason?	Yes / No
5. Do you understand that any information which suggests that a young person is at risk of harm will have to be passed on to the school counsellor and/or school principal?	Yes / No
6. Are you happy to take part in a 30-minute group discussion with a researcher and other pupils?	Yes / No
7. Are you happy for the group discussion to be tape recorded?	Yes / No
8. Do you agree to take part in this study?	Yes / No

Please write and sign your name or initials and today's date below.

Signature or Initials

Date

Keep one copy of this form for yourself and give the other one to the researcher. Thank you very much!!



Information about the Research Pupils

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

Hi, my name is Maria and I work along with Áine and others at Queen's University Belfast. We would like to invite you to take part in a research study. Before you decide whether you wish to take part, you need to understand why the research is being done, and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish.

What is the purpose of the study?

Teenage girls who have an unplanned pregnancy face emotional and practical problems as well as risks to their health. Teenage boys' health and wellbeing can also be affected by teenage pregnancy and young men have an important role to play in preventing unintended pregnancy. The overall aim of this study is to test an educational resource based around an interactive film that is designed to help young people (boys and girls) avoid an unintended pregnancy.

What is the educational resource?

The resource is designed for use at Key Stage 4 within the Personal Development strand of the *Learning for Life and Work* curriculum and has been developed in close consultation with health and education experts, teachers, parents and pupils. It includes the following:

- v. An interactive film about a 16-year old boy who has just found out that his girlfriend is unexpectedly pregnant;
- vi. Four RSE lessons with specific classroom-based and homework activities which include group discussions, role-plays, worksheets, and a parent-pupil exercise;
- vii. An information and discussion session for parents/guardians delivered by RSE teachers; and
- viii. Detailed information brochures and factsheets about the resource and unintended teenage pregnancy in general for schools, teachers, pupils and parents/guardians.

Why have I been invited?

We are asking all Year 11 pupils in seven post-primary schools in Northern Ireland to take part in the research. You have been invited because you are part of this group.

Do I have to take part?

No. It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. We will give you a copy of the consent form to keep. You can decide not to take part and you do not have to give a reason for saying no. You are free to withdraw at any time, without giving a reason. If you do withdraw we will not use the information we have collected from you.

What about my parents/guardians?

We will send an information sheet to your parents or guardians so that, if you wish, you can discuss the study with them and decide together whether you would like to take part. Your parents have also been given the right to withdraw you from the study by signing an 'opt out' form and returning it to the researcher.

What will I be asked to do if I take part?

Of the 7 schools who agree to participate, 4 will be randomly assigned to the 'intervention group' and 3 will be randomly assigned to the 'comparison group'. Teachers and pupils in the intervention group schools will be asked to use the educational resource during four weekly RSE lessons and those in the comparison group will continue with normal RSE lessons. At the end of the study we will compare the results of questionnaires completed by pupils in the two groups to see if it is possible to measure the impact of the educational resource on pupils' knowledge, communication skills, intentions to avoid teenage pregnancy and sexual risk-taking behaviour.

All Year 11 pupils in the 7 participating schools will complete the same questionnaire on three occasions over a 12-month period (at the beginning of the research and 5 and 9 months later). The questionnaire will contain questions about your knowledge of teenage pregnancy; sexual experience; use of contraception; diagnosis of sexually transmitted infections; and comfort communicating about sexual relationships and teenage pregnancy with parents/guardians, partners and peers.

Pupils in *intervention group schools* will receive the educational resource during four consecutive RSE lessons. Around 5 pupils from each Year 11 class will also be asked to take part in a 30 minute focus group discussion with a researcher regarding the acceptability and feasibility of the resource and participation in the research.

In addition to completing the questionnaire on three occasions over a 12-month period, a sample of pupils in *comparison group schools* (two groups of 5) will be asked to take

part in a 30 minute focus group discussion with a researcher regarding the acceptability of the questionnaire.

Will we tell anyone what you say or do during the research?

No. You will not be asked to put your name on the questionnaire and the researchers will not use the names of individuals or schools when they write about the research. However, if you say anything during the research that makes the researcher think that you or another young person is at risk of harm the researcher will have to talk to the school counsellor and/or principal about it.

What if something upsets you?

We hope that you will enjoy taking part in the study. However, if you feel in any way upset as a result of taking part or unhappy with anything that happens during the study you can talk to your parents/guardians, your teachers or to the researchers.

What will happen to the results of the research study?

The results of the study will be published in research reports and in scientific journals. We will not publish anything that could be used to identify you or your school. We will send copies of reports and journal articles to your school so that you can read them if you want to.

Further information and contact details

If you would like further information about the research, please contact Dr Áine Aventin or Dr Maria Lohan.

Dr Áine Aventin
Research Fellow

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Dr Maria Lohan
Senior Lecturer

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

What if I want to make a complaint?

If you are unhappy with any part of the study and do not wish to approach the research team, please contact Dr Oliver Perra, Chair of the Research Ethics Committee of the School of Nursing and Midwifery, Queen's University Belfast.

Dr Oliver Perra





Consent Form

Pupils

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

	Please circle answer
1. Have you read the information sheet?	Yes / No
2. Have you had a chance to think about the information and ask questions?	Yes / No
3. Do you understand what the research is about?	Yes / No
4. Do you understand that it's OK to stop taking part at any time without giving a reason?	Yes / No
5. Do you understand that any information which suggests that a young person is at risk of harm will have to be passed on to the school counsellor and/or school principal?	Yes / No
6. Do you understand that you may or may not use the educational resource (depending on whether your school is placed in the intervention or comparison group)?	Yes / No
7. If you do use the resource, are you happy for the researcher to observe you and your classmates during one RSE lesson?	Yes / No
8. Are you happy to fill in a questionnaire during an RSE lesson on three different occasions over a one-year period?	Yes / No
9. Are you happy to take part in a 30-minute group discussion with a researcher and other pupils?	Yes / No
10. Are you happy for the discussion to be tape recorded?	Yes / No

11. Do you agree to take part in this study?	Yes / No
--	----------

Please write and sign your name or initials and today's date below.

Signature or Initials

Date

**Keep one copy of this form for yourself and give the other one to the researcher. Thank
you very much!!**



Information about the Research

FOCUS GROUPS

Pupils Intervention Group

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

You have already been a participant in the first part of this research by completing a questionnaire and using the *If I Were Jack* resource. Thank you for your time and cooperation in this stage of the research.

You have now been randomly selected to take part in the next stage of the research which involves participating in a focus group discussion. You will be again asked to give your consent to participate and offered the chance to withdraw without giving a reason.

This part of the research will mean a group of up to 10 pupils meeting with a researcher for 30 minutes. The researcher will ask the participants to discuss their experiences of using the resource and taking part in the research. The conversation will be tape recorded so that at a later stage we can write out the discussion and see where pupils agree and disagree. All identifying features of you and your school will be removed from the written version.

You were provided with an Information Sheet before completing the questionnaire that provided information about the study, and that Information Sheet was yours to take away with you. We will also remind you here what the study is about, and emphasise that this Information Sheet is also yours to take away. We will also remind you about other important issues that were raised in the first Information Sheet that we provided.

A reminder of the purpose of the study

Teenage girls who have an unplanned pregnancy face emotional and practical problems as well as risks to their health. Teenage boys' health and wellbeing can also be affected by teenage pregnancy and young men have an important role to play in preventing unintended pregnancy. The overall aim of this study is to test an educational resource based around an interactive film that is designed to help young people (boys and girls) avoid an unintended pregnancy.

Do I have to take part?

No. It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. We will give you a copy of the consent form to keep. You can decide not to take part and you do not have to give a reason for saying no. You are free to withdraw at any time, without giving a reason. If you do withdraw we will not use the information we have collected from you.

Will we tell anyone what you say or do during the research?

No. You will not be asked to put your name on the questionnaire and the researchers will not use the names of individuals or schools when they write about the research. However, if you say anything during the research that makes the researcher think that you or another young person is at risk of harm the researcher will have to talk to the school counsellor and/or principal about it.

What if something upsets you?

We hope that you will enjoy taking part in the study. However, if you feel in any way upset as a result of taking part or unhappy with anything that happens during the study you can talk to your parents/guardians, your teachers or to the researchers.

What will happen to the results of the research study?

The results of the study will be published in research reports and in scientific journals. We will not publish anything that could be used to identify you or your school. We will send copies of reports and journal articles to your school so that you can read them if you want to.

Further information and contact details

If you would like further information about the research, please contact Dr Áine Aventin or Dr Maria Lohan.

Dr Áine Aventin
Research Fellow



Dr Maria Lohan
Senior Lecturer



What if I want to make a complaint?

If you are unhappy with any part of the study and do not wish to approach the research team, please contact Dr Oliver Perra, Chair of the Research Ethics Committee of the School of Nursing and Midwifery, Queen's University Belfast.

Dr Oliver Perra





Consent Form
FOCUS GROUPS
Pupils Intervention Group

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

	Please circle answer
1. Have you read the information sheet?	Yes / No
2. Have you had a chance to think about the information and ask questions?	Yes / No
3. Do you understand what the research is about?	Yes / No
4. Do you understand that it's OK to stop taking part at any time without giving a reason?	Yes / No
5. Do you understand that any information which suggests that a young person is at risk of harm will have to be passed on to the school counsellor and/or school principal?	Yes / No
6. Are you happy to take part in a 30-minute group discussion with a researcher and other pupils?	Yes / No
7. Are you happy for the group discussion to be tape recorded?	Yes / No
8. Do you agree to take part in this study?	Yes / No

Please write and sign your name or initials and today's date below.

Signature or Initials

Date

Keep one copy of this form for yourself and give the other one to the researcher. Thank you very much!!



Information about the Research

FOCUS GROUPS

Pupils Comparison Group

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

You have already been a participant in the first part of this research by completing a questionnaire. Thank you for your time and cooperation in this stage of the research.

You have now been randomly selected to take part in the next stage of the research which involves participating in a focus group discussion. You will be again asked to give your consent to participate and offered the chance to withdraw without giving a reason.

This part of the research will mean a group of up to 10 pupils meeting with a researcher for 30 minutes. The researcher will ask the participants to discuss the questions included in the questionnaire. The conversation will be tape recorded so that at a later stage we can write out the discussion and see where pupils agree and disagree. All identifying features of you and your school will be removed from the written version.

You were provided with an Information Sheet before completing the questionnaire that provided information about the study, and that Information Sheet was yours to take away with you. We will also remind you here what the study is about, and emphasise that this Information Sheet is also yours to take away. We will also remind you about other important issues that were raised in the first Information Sheet that we provided.

A reminder of the purpose of the study

Teenage girls who have an unplanned pregnancy face emotional and practical problems as well as risks to their health. Teenage boys' health and wellbeing can also be affected by teenage pregnancy and young men have an important role to play in preventing unintended pregnancy. The overall aim of this study is to test an educational resource based around an interactive film that is designed to help young people (boys and girls) avoid an unintended pregnancy.

Do I have to take part?

No. It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. We will give you a copy of the consent form to keep. You can decide not to take part and you do not have to give a reason for saying no. You are free to withdraw at any time, without giving a reason. If you do withdraw we will not use the information we have collected from you.

Will we tell anyone what you say or do during the research?

No. You will not be asked to put your name on the questionnaire and the researchers will not use the names of individuals or schools when they write about the research. However, if you say anything during the research that makes the researcher think that you or another young person is at risk of harm the researcher will have to talk to the school counsellor and/or principal about it.

What if something upsets you?

We hope that you will enjoy taking part in the study. However, if you feel in any way upset as a result of taking part or unhappy with anything that happens during the study you can talk to your parents/guardians, your teachers or to the researchers.

What will happen to the results of the research study?

The results of the study will be published in research reports and in scientific journals. We will not publish anything that could be used to identify you or your school. We will send copies of reports and journal articles to your school so that you can read them if you want to.

Further information and contact details

If you would like further information about the research, please contact Dr Áine Aventin or Dr Maria Lohan.

Dr Áine Aventin
Research Fellow

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Dr Maria Lohan
Senior Lecturer

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

What if I want to make a complaint?

If you are unhappy with any part of the study and do not wish to approach the research team, please contact Dr Oliver Perra, Chair of the Research Ethics Committee of the School of Nursing and Midwifery, Queen's University Belfast.

Dr Oliver Perra

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]



Consent Form
FOCUS GROUPS
Pupils Comparison Group

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

	Please circle answer
1. Have you read the information sheet?	Yes / No
2. Have you had a chance to think about the information and ask questions?	Yes / No
3. Do you understand what the research is about?	Yes / No
4. Do you understand that it's OK to stop taking part at any time without giving a reason?	Yes / No
5. Do you understand that any information which suggests that a young person is at risk of harm will have to be passed on to the school counsellor and/or school principal?	Yes / No
6. Are you happy to take part in a 30-minute group discussion with a researcher and other pupils?	Yes / No
7. Are you happy for the group discussion to be tape recorded?	Yes / No
8. Do you agree to take part in this study?	Yes / No

Please write and sign your name or initials and today's date below.

Signature or Initials

Date

**Keep one copy of this form for yourself and give the other one to the researcher. Thank
you very much!**

SCHOOL DOCUMENTS

Letter to schools - questionnaire development

Information sheet for schools - questionnaire development

Consent form for schools - questionnaire development

Letter to schools - feasibility study

Information sheet for schools - feasibility study

Consent form for schools - feasibility study



Dr Maria Lohan

Senior Lecturer

[REDACTED]
[REDACTED]
[REDACTED]

[DATE]

[SCHOOL ADDRESS]

RE: Research study - Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

Dear [PRINCIPAL NAME,]

I am writing to invite your Year 11 pupils to participate in a research study. The overall aim of the research is to examine the acceptability and practicality of using and evaluating a unique and scientifically informed educational resource on the topic of teenage men and unintended pregnancy in post-primary schools in Northern Ireland. The aim of the educational resource is to increase boys' as well as girls' intention to avoid an unintended teenage pregnancy. The resource was developed by a research team at Queen's University Belfast in collaboration with key stakeholders in Northern Ireland which include the Department of Health, Social Services and Public Safety Northern Ireland, the Public Health Agency Northern Ireland and the Council for Curriculum Education and Assessment Northern Ireland (CCEA). The research is funded by the UK National Institute for Health Research.

A preliminary aim of the study is to develop a brief questionnaire which will enable us to gauge the impact of the resource on a range of outcomes including young people's knowledge, communication skills, intentions to avoid unplanned teenage pregnancy, and

sexual risk-taking behaviour. *It is for this preliminary part of the study that we request your pupils' participation.*

We would like to invite approximately 50-60 male and female Year 11 pupils to complete an online version the questionnaire. Additionally, we would require a sample of these pupils (approximately 10) to take part in a focus group discussion with a trained researcher regarding the acceptability of the questions included in the questionnaire. The questionnaire takes around 25 minutes to complete and the focus group discussions an additional 30 minutes. We would therefore require access to 50-60 Year 11 pupils for one class period and further access to 10 of these pupils for one additional class period. These sessions would be arranged at a time that is convenient for you in May 2014.

We would value your participation in this research, as your contribution would inform a process of generating knowledge about effective sexual health resources for young people in Northern Ireland. Your contact details have been passed to us by Joanna Gregg (Sexual Health Co-coordinator, Belfast Trust) in her capacity as a member of our expert advisory group. Participation is, however, entirely voluntary and you or your pupils are under no obligation to take part. Should you agree to participate we would provide you with £150 to cover the cost of addressing and posting consent forms and information sheets to the parents/guardians of participating pupils.

I have enclosed an information sheet which provides a brief overview of the research along with a copy of the questionnaire and focus group topic guide. A member of my team will contact you within the next week to offer you an opportunity to discuss the study further and see if you are happy to participate.

Yours sincerely,



Dr Maria Lohan



Information about the Research (Questionnaire Development Study) Schools

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

We would like to invite a sample of your Year 11 pupils to take part in a research study. Before you decide whether you wish to participate, you should understand why the research is being done, and what it would involve for you and your pupils. Please take time to read the following information carefully.

Who is organising and funding the research?

The research is funded by the UK National Institute for Health Research Public Health Research Programme (NIHR PHR). The NIHR PHR funds research to evaluate non-NHS interventions intended to improve the health of the public and reduce inequalities in health. The research will be conducted by a team of researchers from Queen's University Belfast. The research project starts in May 2014, and is due to be completed in April 2016.

What is the purpose of the study?

Teenage women who have an unplanned pregnancy face serious emotional and practical problems as well as risks to their health. Young men's health and wellbeing can also be affected by teenage pregnancy and young men have an important role to play in preventing unintended pregnancy. The overall aim of this study is to test the acceptability and practicality of introducing a resource which is designed to help teenage boys as well as girls avoid an unintended pregnancy. A preliminary aim of the study is to develop a brief questionnaire which will enable us to gauge the impact of the resource on a range of outcomes including young people's knowledge, communication skills, intentions to avoid unplanned teenage pregnancy, and sexual risk-taking behaviour.

The resource is designed for use at Key Stage 4 within the Personal Development Strand of the *Learning for Life and Work* curriculum and has been developed in close consultation with health and education experts (including the Public Health Agency Northern Ireland and the

Council for Curriculum Education and Assessment Northern Ireland [CCEA]) as well as teachers, parents and pupils. **We wish to emphasise and reassure you that the content of the resource and questionnaire being used in the research do not contain any material that is sexually explicit.** The focus is on educating young people about unintended teenage pregnancy with a particular emphasis on the roles and responsibilities of teenage men in relation to this.

Why has my school been invited?

We are asking 50-60 Year 11 pupils to take part in the questionnaire development phase of the research. Your school is being invited to take part because your contact details have been passed to us by Joanna Gregg (Sexual Health Co-coordinator, Belfast Trust) in her capacity as a member of our expert advisory group.

Do my pupils have to take part?

No. It is up to you, them and their parents to decide. In the first instance, if you decide after having read this information sheet that you would prefer your pupils not to take part in this research, you can indicate this to the research team and no further action will be taken. If, however, you are happy for your pupils to take part in the research, we will provide you with similar information sheets and consent forms for pupils and parents. In order for individual pupils to participate they will need to complete a consent form indicating their willingness to take part. Pupils can decide not to take part and do not have to give a reason for saying no. Additionally, parents/guardians will be provided with information about the research and requested to return a form to the research team if they wish for their son/daughter to opt-out of the research. Pupils whose parents wish them to opt-out of the research will not participate.

What if my pupils or their parents/guardians decide to withdraw from the study?

Your pupils and/or their parents/guardians are free to withdraw at any time, without giving a reason. If one of your pupils and/or their parents/guardians does withdraw we will not use the data we have collected from them.

What will my pupils be asked to do if they take part?

There are two parts in the study. We would like 50-60 Year 11 pupils to participate in Part One, and a smaller number of pupils at Part Two.

Part one: If you agree to your pupils taking part at stage one, they will be asked to fill in a questionnaire about their: knowledge of ways to avoid teenage pregnancy and the possible negative consequences of unintended teenage pregnancy; sexual experience; use of contraception; diagnosis of sexually transmitted infections; comfort communicating about sexual relationships and teenage pregnancy with parents, partners and peers; and strength of their intention to avoid pregnancy during adolescence.

This should take no more than 25 minutes and will happen on school premises. Part two will take place directly afterwards.

Part two: A random selection of around 10 pupils will be chosen to participate in Part two which is a focus group discussion. Pupils selected to take part in the focus group, will be again asked to give their consent to participate and offered the chance to withdraw without giving a reason. This part of the research will mean two groups of around 5 young men and women who have completed the questionnaire meeting with a researcher for 30 minutes. The researcher will ask the pupils to give their views on the acceptability of the questions included in the questionnaire. The conversation will be tape recorded so that we can write out the discussion and see where the pupils agree and disagree. All identifying features of your pupils and the school will be removed from the written version.

What if there is a problem?

If your pupils are unhappy with anything that happens during the study they can talk to their parents and teachers, or to the researchers. If an issue is brought to the attention of the researchers, we will deal with it immediately. If pupils show any signs of visible distress, we will inform the school counsellor. Again, pupils can withdraw from the study at any time, without giving a reason. They can also make a formal complaint if they wish (details of how to do this are set out at the end of this document).

Will our taking part in the study be kept confidential?

All information gathered during the course of the research will be kept strictly confidential unless child protection, illegal or professional misconduct issues arise. If anything is disclosed during the course of the research that suggests that an individual is involved in or at risk of harmful or criminal activity the researcher will be obliged to pass this information on to the relevant authorities.

Only the researchers will have access to the data. We will follow ethical and legal guidelines and keep all information privately and securely. Your pupils will not be

asked to put their names or the name of the school on the questionnaire. We will store the questionnaires and all other paper data in a locked filing cabinet in a secure building at Queen's University Belfast. Names of individuals or schools stored on a computer will be password protected and deleted at the end of the study. Paper data will be destroyed securely five years after the study ends. We will listen to the tapes of the focus group interviews and write down what is said. We will not write down names or anything else that would identify any individual.

At the end of the study, all data resulting from the research (including the tapes and transcripts) will be stored for a minimum of 5 years and a maximum of 10 years in Queen's University Belfast. All data will be archived by year 10 in The UK Data Archive (UKDA) located in the University of Essex. This is a centre that specialises in keeping data securely so that other researchers can apply for ethical permission to use it in their own research.

Will we be asked to participate in any other part of the study?

The next stage of the study involves testing the acceptability and practicality of using and evaluating a unique and scientifically informed educational resource on the topic of teenage men and unintended pregnancy in seven post-primary schools in Northern Ireland (NI). The research will examine the value and practical issues surrounding the conduct of a randomised controlled trial which would find out whether or not this resource can improve young people's sexual health knowledge and behaviours over the medium and longer term. If you would like more information about this part of the study, please indicate your interest to the researcher.

What will happen to the results of the research study?

The results of the study will be published in research reports and in scientific journals. We will not publish anything that could be used to identify you, your pupils or the school. We will send copies of reports and journal articles to your school so that participants can read them if they want to.

Who has reviewed the study?

All research is looked at by independent group of people, called a Research Ethics Committee, to protect all participants' safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Research Ethics Committee of the School of Nursing and Midwifery, Queen's University Belfast.

Further information and contact details

If you would like further information about the research, please contact Dr Áine Aventin or Dr Maria Lohan.

Dr Áine Aventin
Research Fellow

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Dr Maria Lohan
Senior Lecturer

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

What if I want to make a complaint?

If you and/or your pupils are unhappy with any part of the study and do not wish to approach the research team, please contact: Dr Oliver Perra, Chair of the Research Ethics Committee, School of Nursing and Midwifery, Queen's University Belfast, 97 Lisburn Road, Belfast BT9 7BL.



Consent Form

(Questionnaire Development Study)

School Principals

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

	Please circle answer
1. I have read and understood the information sheet dated (version).	Yes / No
2. I understand what the research is about.	Yes / No
3. I understand that my Year 11 pupils will only take part in the research if they agree to do so and that it is OK for them to stop taking part at any time without giving a reason.	Yes / No
4. I understand that relevant sections of data collected during the study may be looked at by responsible individuals from the research team, and that information gathered will be stored securely, coded anonymously and presented in aggregate form so that no individual or organisation is recognisable.	Yes / No
5. I understand that all information gathered during the course of the research will be kept strictly confidential unless child protection, illegal or professional misconduct issues arise. If anything is disclosed during the course of the research that suggests that an individual is involved in or at risk of harmful or criminal activity the researcher will be obliged to pass this information on to the relevant authorities.	Yes / No
6. I consider my Year 11 pupils to possess the maturity to understand what would be involved in taking part in the research.	Yes / No
7. I consider it appropriate for my Year 11 pupils to take part in the research study.	Yes / No
8. I give my permission for my Year 11 pupils to take part in the study according to the conditions outlined in the information sheet.	Yes / No

Please write and sign your name and insert today's date below.

Your Name**Signature****Date**

Keep one copy of this form for yourself and return the other one to the researcher. Thank you!



Dr Maria Lohan

Senior Lecturer

[REDACTED]
[REDACTED]
[REDACTED]

[DATE]

[SCHOOL ADDRESS]

RE: Research study - Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

Dear [PRINCIPAL NAME],

I am writing to invite you and some of your staff and pupils to participate in a research study. The overall aim of the research is to examine the acceptability and practicality of using and evaluating a unique and scientifically informed educational resource on the topic of teenage men and unintended pregnancy in post-primary schools in Northern Ireland. The aim of the educational resource is to increase boys' as well as girls' intention to avoid an unintended teenage pregnancy.

The resource was developed by a research team at Queen's University Belfast in collaboration with key stakeholders in Northern Ireland which include the Department of Health, Social Services and Public Safety Northern Ireland, the Public Health Agency Northern Ireland, the Council for Curriculum Education and Assessment Northern Ireland (CCEA) as well as teachers, parents and pupils. It is designed to fit within the Personal Development strand of the Learning for Life and Work curriculum and to be used at Key Stage 4.

We would value your participation in this research, as your contribution would inform a process of generating knowledge about effective sexual health resources for young people in Northern Ireland. I have enclosed an information sheet which provides an overview of the research. A member of my team will contact you within the next week to offer you an opportunity to discuss the study further and see if you are happy to participate.

Yours sincerely,



Dr Maria Lohan



Queen's University
Belfast

Information about the Research School Principals

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

We would like to invite you, some of your staff team and all of your Year 11 pupils to take part in a research study. Before you decide whether you wish to participate, you should understand why the research is being done, and what it would involve for you, your staff and pupils. Please take time to read the following information carefully.

Who is organising and funding the research?

The research is funded by the UK National Institute for Health Research Public Health Research Programme (NIHR PHR). The NIHR PHR funds research to evaluate non-NHS interventions intended to improve the health of the public and reduce inequalities in health. The research will be conducted by a team of researchers from Queen's University Belfast. The research project starts in May 2014, and is due to be completed in April 2016.

What is the purpose of the study?

Teenage women who have an unplanned pregnancy face serious emotional and practical problems as well as risks to their health. Young men's health and wellbeing can also be affected by teenage pregnancy and young men have an important role to play in preventing unintended pregnancy. The overall aim of this study is to test the acceptability and practicality of introducing an educational resource which is designed to help teenage boys as well as girls avoid an unintended pregnancy.

What is the educational resource?

The resource is designed for use at Key Stage 4 within the *Personal Development* strand of the *Learning for Life and Work* curriculum and has been developed in close consultation with health and education experts (including the Public Health Agency Northern Ireland and the Council for Curriculum Education and Assessment Northern Ireland [CCEA]) as well as teachers, parents and pupils. It includes the following components:

- ix. An interactive film about a 16-year old boy who has just found out that his girlfriend is unexpectedly pregnant;

- x. Classroom materials for teachers containing four detailed lesson plans with specific classroom-based and homework activities which include group discussions, role-plays, worksheets, and a parent-pupil exercise;
- xi. 60-minute face-to-face training session for teachers wishing to implement the intervention delivered by a researcher;
- xii. 60-minute information and discussion session for parents/guardians delivered by RSE teachers; and
- xiii. Detailed information brochures and factsheets about the resource and unintended teenage pregnancy in general for schools, teachers, pupils and parents.

We wish to emphasise and reassure you that the content of the resource and questionnaires being used in the research do not contain any material that is sexually explicit. The focus is on educating young people about unintended teenage pregnancy with a particular emphasis on the roles and responsibilities of teenage men in relation to this.

Why has my school been invited?

We are asking seven post-primary schools in Northern Ireland to participate in the research. We are aiming to recruit a mix of schools in terms of management type and location. Your school is being invited to take part because it meets our recruitment criteria and one of your teachers attended an RSE training day and expressed an interest in participating **or** your school has been randomly selected from a list of schools which meet our recruitment criteria.

Do we have to take part?

No. It is up to you, your staff, your pupils and their parents to decide. If you decide after having read this information sheet that you would prefer not to take part in this research, you can indicate this to the research team and no further action will be taken. If, however, you are happy to hear more about the study a researcher will be happy to provide you and your RSE teachers with more information (via telephone or a face-to-face meeting at your school).

If after speaking with the researcher you decide you are happy for your school to take part in the research, we will provide similar information sheets and consent forms for teachers, pupils and parents. In order for individual teachers and pupils to participate they will need to complete a consent form indicating their willingness to take part. Pupils and teachers can decide not to take part and do not have to give a reason for saying no. Additionally, parents/guardians will be provided with information about the research and requested to return a form to the research team if they wish for their child

to opt-out of the research. Pupils whose parents wish them to opt-out of the research will not participate.

What if my staff, pupils or their parents/guardians decide to withdraw from the study?

All participants are free to withdraw at any time, without giving a reason. If this happens we will not use the data we have collected from them.

What will we be asked to do if we take part?

Different participants will be asked to do different things:

Schools: Of the 7 recruited schools, 4 will be randomly assigned to the 'intervention group' and 3 will be randomly assigned to the 'comparison group'. Schools in the intervention group will be asked to use the educational resource during four weekly RSE lessons and those in the comparison group will continue with normal RSE practice. At the end of the study we will compare the results of questionnaires completed by pupils in the two groups to see if it is possible to measure the impact of the educational resource on pupils' knowledge, communication skills, intentions to avoid teenage pregnancy and sexual risk-taking behaviour.

Principals and Heads of Year 11: Principals and/or Heads of Year 11 in all schools will be asked to take part in an interview with a researcher about current RSE practice in the school and experiences of taking part in the research. This would take a maximum of 60 minutes.

Year 11 RSE Teachers: Teachers in *intervention group schools* will be provided with a 60-minute training session regarding the use of the resource and facilitation of parents' information and discussion session. They will then be asked to deliver the resource to Year 11 pupils during four consecutive RSE lessons. They will also be asked to facilitate a 60-minute parents' information and discussion session and to be in the room when a researcher delivers the questionnaires to pupils during an RSE lesson (3 times over a 12 month period). Finally, teachers will be asked to take part in an interview with a researcher (max 60-minutes) regarding the acceptability and feasibility of the resource and participation in the research. In total this requires 6.5 hours of a teacher's time over a 12-month period (not including lesson preparation time).

Teachers in *comparison group schools* will be asked to be in the room when a researcher delivers the questionnaires to pupils (3 times over a 12 month period) and take part in an interview with a researcher (max 60-minutes) regarding the acceptability and feasibility of participation in the research. This would require 2.5 hours of the teachers' time over a 12-month period.

Year 11 Pupils: All Year 11 pupils in all 7 schools will complete the same questionnaire on three occasions over a 12-month period (at the beginning of the research and 5 and 9 months later).

Pupils in *intervention group schools* will receive the educational resource during four consecutive RSE lessons. Approximately 5-8 pupils from each Year 11 class will be asked to take part in a 30 minute focus group discussion with a researcher regarding the acceptability and feasibility of the resource and participation in the research.

In addition to completing the questionnaire on three occasions over a 12-month period, a sample of pupils in *comparison group schools* (two groups of 5-8) will be asked to take part in a 30 minute focus group discussion with a researcher regarding the acceptability of the questionnaire.

Parents of Year 11 Pupils: All parents of pupils in *intervention group schools* will be invited to participate in a 60-minute parents' information and discussion session at the school facilitated by an RSE teacher. The session will include information about the resource and discussion around how best to talk to teenagers about avoiding unintended pregnancy. A sample of these parents (approximately 5 -8) will be invited to take part in a group discussion with the researcher regarding the acceptability and feasibility of the resource and the discussion session. Parents will also be asked to participate in a short homework exercise with their child as part of the intervention in which they answer their child's questions about their views on teenage pregnancy. Following this homework exercise they will be sent a link to a short online survey regarding their experiences of this and (if appropriate) the parent/guardian information session.

Parents of pupils in *comparison group schools* will not be invited to participate in the research.

Administration staff: In order to maintain participant confidentiality, administration staff in all 7 schools will be asked to address and post envelopes containing information sheets and opt-out forms for the parents of Year 11 pupils.

Administrators in *intervention group schools* will send a second letter or email to parents of Year 11 pupils inviting them to a parents' information and discussion session and a third letter or email to parents with a request for them to complete a short online survey.

Administration staff will be asked to record time and resources spent on these activities and we will reimburse all expenses.

The timetable below summarises what participants in intervention and comparison group schools would be asked to do during the study. *Please note: in line with best practice recommendations, schools will not be randomly assigned to intervention or comparison groups until after pupils have completed the questionnaire for the first time.*

Research Timetable

DATE	INTERVENTION SCHOOLS	COMPARISON SCHOOLS
May 2014	Principal/RSE teachers consent to participate	Principal/RSE teachers consent to participate
Sept – Oct 2014	Parents sent information about the research	Parents sent information about the research
Dec 2014	<p>Pupils consent to participate & complete questionnaire during 1 RSE lesson</p> <p>School notified of allocation to intervention group</p> <p>Principal or Head of Year 11 interview (<i>current RSE practice in school</i>)</p>	<p>Pupils consent to participate & complete questionnaire during 1 RSE lesson</p> <p>School notified of allocation to comparison group</p>
Jan – Feb 2015	<p>60 minute teacher training session</p> <p>Teacher delivers resource over 4 consecutive RSE lessons</p> <p>Teacher delivers parents' information session</p> <p>Researcher observes one RSE lesson and one parents' information session in each school</p>	
Mar - 2015	Focus groups pupils, focus group sparents and interviews RSE teachers (<i>acceptability and feasibility of the resource</i>)	
June 2015	Pupils complete questionnaire during 1 RSE lesson	Pupils complete questionnaire during 1 RSE lesson

Sept - Oct 2015	<p>Pupils complete questionnaire during 1 RSE lesson</p> <p>interviews with RSE teachers (<i>acceptability and feasibility of participation in research</i>)</p>	<p>Pupils complete questionnaire during 1 RSE lesson</p> <p>Focus groups with pupils (<i>acceptability of questionnaire</i>)</p> <p>Interviews teachers or principals (<i>acceptability of participation in research and current RSE provision in schools</i>)</p>
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What are the benefits of taking part?

The research would provide you, your team and pupils with an opportunity to be involved in the evaluation of an innovative relationship and sexuality education resource that is designed to decrease unintended teenage pregnancy. The findings will be widely shared and should help to inform future policy and practice regarding pregnancy education for young people in Northern Ireland.

What if there is a problem?

If you, your staff or pupils are unhappy with anything that happens during the study they can talk to the researchers. If an issue is brought to the attention of the researchers, we will deal with it immediately. If pupils show any signs of visible distress, we will inform the school counsellor. Participants can also make a formal complaint if they wish (details of how to do this are set out at the end of this document).

Will our taking part in the study be kept confidential?

All information gathered during the course of the research will be kept strictly confidential unless child protection, illegal or professional misconduct issues arise. If anything is disclosed during the course of the research that suggests that an individual is involved in or at risk of harmful or criminal activity the researcher will be obliged to pass this information on to the relevant authorities.

Only the researchers will have access to the data. We will follow ethical and legal guidelines and keep all information privately and securely. Your pupils will not be asked to put their names or the name of the school on the questionnaire. We will store the questionnaires and all other paper data in a locked filing cabinet in a secure building at Queen's University Belfast. Names of individuals or schools stored on a computer will be password protected and deleted at the end of the study. Paper data will be destroyed securely five years after the study ends. We will listen to the tapes of the focus group

interviews and write down what is said. We will not write down names or anything else that would identify any individual or school.

At the end of the study, all data resulting from the research (including the tapes and transcripts) will be stored for a minimum of 5 years and a maximum of 10 years in Queen's University Belfast. All data will be archived by year 10 in The UK Data Archive (UKDA) located in the University of Essex. This is a centre that specialises in keeping data securely so that other researchers can apply for ethical permission to use it in their own research.

What will happen to the results of the research study?

The results of the study will be published in research reports and in scientific journals. We will not publish anything that could be used to identify you, your pupils or the school. We will send copies of reports and journal articles to your school so that participants can read them if they want to.

Who has reviewed the study?

All research is looked at by independent group of people, called a Research Ethics Committee, to protect all participants' safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Research Ethics Committee of the School of Nursing and Midwifery, Queen's University Belfast.

Further information and contact details

If you would like further information about the research, please contact Dr Áine Aventin or Dr Maria Lohan.

Dr Áine Aventin
Research Fellow

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Dr Maria Lohan
Senior Lecturer

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

What if I want to make a complaint?

If you and/or your staff or pupils are unhappy with any part of the study and do not wish to approach the research team, please contact:

Dr Oliver Perra, Chair of the Research Ethics Committee of the School of Nursing and Midwifery, Queen's University Belfast, 97 Lisburn Road, Belfast BT9 7BL



Consent Form

School Principals

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

	Please circle answer
1. I have read and understood the information sheet dated (version).	Yes / No
2. I understand what the research is about.	Yes / No
3. I understand that my Year 11 pupils will only take part in the research if they agree to do so and that it is OK for them to stop taking part at any time without giving a reason.	Yes / No
4. I consider my Year 11 pupils to possess the maturity to understand what would be involved in taking part in the research.	Yes / No
5. I consider it appropriate for my Year 11 pupils to take part in the research study.	Yes / No
6. I understand that relevant sections of data collected during the study may be looked at by responsible individuals from the research team, and that information gathered will be stored securely, coded anonymously and presented in aggregate form so that no individual or organisation is recognisable.	Yes / No
7. I understand that all information gathered during the course of the research will be kept strictly confidential unless child protection, illegal or professional misconduct issues arise. If anything is disclosed during the course of the research that suggests that an individual is involved in or at risk of harmful or criminal activity the researcher will be obliged to pass this information on to the relevant authorities.	Yes / No
8. I understand that the school will be randomly assigned to the intervention group or comparison group after baseline data collection and that only schools in the intervention group will use the educational resource.	Yes / No
9. I give my permission for my Year 11 pupils to take part in the study according to the conditions outlined in the information sheet.	Yes / No

Please write and sign your name and insert today's date below.

Your Name

Date

Signature

Keep one copy of this form for yourself and return the other one to the researcher. Thank you!

TEACHER DOCUMENTS

Letter to teachers - questionnaire development

Information sheet for teachers - questionnaire development

Consent form for teachers - questionnaire development

Letter to teachers - feasibility study

Information sheet for teachers - feasibility study

Consent form for teachers - feasibility study

Information sheet for teachers - interview participation by intervention group – feasibility study

Consent form for teachers - interview participation by intervention group – feasibility study

Information sheet for teachers - interview participation by comparison group – feasibility study

Consent form for teachers - interview participation by comparison group – feasibility study

Information sheet for heads of year - interview participation by intervention group – feasibility study

Consent form for heads of year - interview participation by intervention group – feasibility study



Dr Maria Lohan

Senior Lecturer



[DATE]

RE: Research study - Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

Dear RSE Teacher,

I am writing to invite your Year 11 pupils to participate in a research study. The overall aim of the research is to examine the acceptability and practicality of using and evaluating a unique and scientifically informed educational resource on the topic of teenage men and unintended pregnancy in post-primary schools in Northern Ireland. The aim of the educational resource is to increase boys' as well as girls' intention to avoid an unintended teenage pregnancy.

The resource was developed by a research team at Queen's University Belfast in collaboration with key stakeholders in Northern Ireland which include the Department of Health, Social Services and Public Safety Northern Ireland, the Public Health Agency Northern Ireland and the Council for Curriculum Education and Assessment Northern Ireland (CCEA). The research is funded by the UK National Institute for Health Research.

A preliminary aim of the study is to develop a brief questionnaire which will enable us to gauge the impact of the resource on a range of outcomes including young people's knowledge, communication skills, intentions to avoid unplanned teenage pregnancy, and

sexual risk-taking behaviour. *It is for this preliminary part of the study that we request your pupils' participation.*

We would like to invite approximately 50-60 male and female Year 11 pupils to complete an online version the questionnaire. Additionally, we would require a sample of these pupils (approximately 10) to take part in focus group discussions with trained researchers regarding the acceptability of the questions included in the questionnaire. The questionnaire takes around 25 minutes to complete and the focus group discussions an additional 30 minutes. We would therefore require access to 50-60 Year 11 pupils for one RSE class period and further access to 10 of these pupils for one additional class period. These sessions would be arranged at a time that is convenient for you and your pupils in May 2014.

We would value your pupils' participation in this research, as their contribution would inform a process of generating knowledge about effective sexual health resources for young people in Northern Ireland. Your contact details have been passed to us by Joanna Gregg (Sexual Health Co-coordinator, Belfast Trust) in her capacity as a member of our expert advisory group. Participation is, however, entirely voluntary and you or your pupils are under no obligation to take part.

I have enclosed an information sheet which provides a brief overview of the research along with a copy of the questionnaire and focus group topic guide. A member of my team will contact you within the next week to offer you an opportunity to discuss the study further and see if you are happy to participate. This information has also been sent to the school principal.

Yours sincerely,



Dr Maria Lohan



Information about the Research (Questionnaire Development Study) RSE Teachers

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

We would like to invite a sample of your Year 11 pupils to take part in a research study. Before you decide whether you wish to participate, you should understand why the research is being done, and what it would involve for you and your pupils. Please take time to read the following information carefully.

Who is organising and funding the research?

The research is funded by the UK National Institute for Health Research Public Health Research Programme (NIHR PHR). The NIHR PHR funds research to evaluate non-NHS interventions intended to improve the health of the public and reduce inequalities in health. The research will be conducted by a team of researchers from Queen's University Belfast. The research project starts in May 2014, and is due to be completed in April 2016.

What is the purpose of the study?

Teenage girls who have an unplanned pregnancy face serious emotional and practical problems as well as risks to their health. Young men's health and wellbeing can also be affected by teenage pregnancy and young men have an important role to play in preventing unintended pregnancy. The overall aim of this study is to test the acceptability and practicality of introducing a resource which is designed to help teenage boys as well as girls avoid an unintended pregnancy. A preliminary aim of the study is to develop a brief questionnaire which will enable us to gauge the impact of the resource on a range of outcomes including young people's knowledge, communication skills, intentions to avoid unplanned teenage pregnancy, and sexual risk-taking behaviour.

The resource is designed for use at Key Stage 4 within the *Personal Development* strand of the *Learning for Life and Work* curriculum and has been developed in close consultation with health and education experts (including the Public Health Agency Northern Ireland and the

Council for Curriculum Education and Assessment Northern Ireland [CCEA]) as well as teachers, parents and pupils. **We wish to emphasise and reassure you that the content of the resource and questionnaire being used in the research do not contain any material that is sexually explicit.** The focus is on educating young people about unintended teenage pregnancy with a particular emphasis on the roles and responsibilities of teenage men in relation to this.

Why has my school been invited?

We are asking 50-60 Year 11 pupils to take part in the questionnaire development phase of the research. Your school is being invited to take part because your contact details have been passed to us by Joanna Gregg (Sexual Health Co-coordinator, Belfast Trust) in her capacity as a member of our expert advisory group.

Do my pupils have to take part?

No. It is up to you, them and their parents to decide. In the first instance, if you decide after having read this information sheet that you would prefer your pupils not to take part in this research, you can indicate this to the research team and no further action will be taken. If, however, you are happy for your pupils to take part in the research, we will provide you with similar information sheets and consent forms for pupils and parents. In order for individual pupils to participate they will need to complete a consent form indicating their willingness to take part. Pupils can decide not to take part and do not have to give a reason for saying no. Additionally, parents/guardians will be provided with information about the research and requested to return a form to the research team if they wish for their son/daughter to opt-out of the research. Pupils whose parents wish them to opt-out of the research will not participate.

What if my pupils or their parents/guardians decide to withdraw from the study?

Your pupils and/or their parents/guardians are free to withdraw at any time, without giving a reason. If one of your pupils and/or their parents/guardians does withdraw we will not use the data we have collected from them.

What will my pupils be asked to do if they take part?

There are two parts in the study. We would like 50-60 Year 11 pupils to participate in Part One, and a smaller number of pupils at Part Two.

Part one: If you agree to your pupils taking part at stage one, they will be asked to fill in a questionnaire about their: knowledge of ways to avoid teenage pregnancy and the possible negative consequences of unintended teenage pregnancy; sexual experience; use of contraception; diagnosis of sexually transmitted infections; comfort communicating about sexual relationships and teenage pregnancy with parents, partners and peers; and strength of their intention to avoid pregnancy during adolescence.

This should take no more than 25 minutes and will happen during an RSE lesson on school premises. Part two will take place directly afterwards.

Part two: A random selection of around 10 pupils will be chosen to participate in Part two which is a focus group discussion. Pupils selected to take part in the focus group, will be again asked to give their consent to participate and offered the chance to withdraw without giving a reason. This part of the research will mean two groups of around 5 young men and women who have completed the questionnaire meeting with a researcher for 30 minutes. The researcher will ask the pupils to give their views on the acceptability of the questions included in the questionnaire. The conversation will be tape recorded so that we can write out the discussion and see where the pupils agree and disagree. All identifying features of your pupils and the school will be removed from the written version.

What if there is a problem?

If your pupils are unhappy with anything that happens during the study they can talk to their parents and teachers, or to the researchers. If an issue is brought to the attention of the researchers, we will deal with it immediately. If pupils show any signs of visible distress, we will inform the school counsellor. Again, pupils can withdraw from the study at any time, without giving a reason. They can also make a formal complaint if they wish (details of how to do this are set out at the end of this document).

Will our taking part in the study be kept confidential?

All information gathered during the course of the research will be kept strictly confidential unless child protection, illegal or professional misconduct issues arise. If anything is disclosed during the course of the research that suggests that an individual is involved in or at risk of harmful or criminal activity the researcher will be obliged to pass this information on to the relevant authorities.

Only the researchers will have access to the data. We will follow ethical and legal guidelines and keep all information privately and securely. Your pupils will not be

asked to put their names or the name of the school on the questionnaire. We will store the questionnaires and all other paper data in a locked filing cabinet in a secure building at Queen's University Belfast. Names of individuals or schools stored on a computer will be password protected and deleted at the end of the study. Paper data will be destroyed securely five years after the study ends. We will listen to the tapes of the focus group interviews and write down what is said. We will not write down names or anything else that would identify any individual.

At the end of the study, all data resulting from the research (including the tapes and transcripts) will be stored for a minimum of 5 years and a maximum of 10 years in Queen's University Belfast. All data will be archived by year 10 in The UK Data Archive (UKDA) located in the University of Essex. This is a centre that specialises in keeping data securely so that other researchers can apply for ethical permission to use it in their own research.

Will we be asked to participate in any other part of the study?

The next stage of the study involves testing the acceptability and practicality of using and evaluating a unique and scientifically informed educational resource on the topic of teenage men and unintended pregnancy in seven post-primary schools in Northern Ireland (NI). The research will examine the value and practical issues surrounding the conduct of a randomised controlled trial which would find out whether or not this resource can improve young people's sexual health knowledge and behaviours over the medium and longer term. If you would like more information about this part of the study, please indicate your interest to the researcher.

What will happen to the results of the research study?

The results of the study will be published in research reports and in scientific journals. We will not publish anything that could be used to identify you, your pupils or the school. We will send copies of reports and journal articles to your school so that participants can read them if they want to.

Who has reviewed the study?

All research is looked at by independent group of people, called a Research Ethics Committee, to protect all participants' safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Research Ethics Committee of the School of Nursing and Midwifery, Queen's University Belfast.

Further information and contact details

If you would like further information about the research, please contact Dr Áine Aventin or Dr Maria Lohan.

Dr Áine Aventin
Research Fellow

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Dr Maria Lohan
Senior Lecturer

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

What if I want to make a complaint?

If you and/or your pupils are unhappy with any part of the study and do not wish to approach the research team, please contact Dr Oliver Perra, Chair of the Research Ethics Committee of the School of Nursing and Midwifery, Queen's University Belfast.

Dr Oliver Perra

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]



Consent Form

(Questionnaire Development Study)

RSE Teachers

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

	Please circle answer
1. I have read and understood the information sheet dated (version).	Yes / No
2. I understand what the research is about.	Yes / No
3. I understand that my Year 11 pupils will only take part in the research if they agree to do so and that it is OK for them to stop taking part at any time without giving a reason.	Yes / No
4. I consider my Year 11 pupils to possess the maturity to understand what would be involved in taking part in the research.	Yes / No
5. I understand that relevant sections of data collected during the study may be looked at by responsible individuals from the research team, and that information gathered will be stored securely, coded anonymously and presented in aggregate form so that no individual or organisation is recognisable.	Yes / No
6. I understand that all information gathered during the course of the research will be kept strictly confidential unless child protection, illegal or professional misconduct issues arise. If anything is disclosed during the course of the research that suggests that an individual is involved in or at risk of harmful or criminal activity the researcher will be obliged to pass this information on to the relevant authorities.	Yes / No
7. I consider it appropriate for my Year 11 pupils to take part in the research study.	Yes / No
8. I give my permission for my Year 11 pupils to take part in the study according to the conditions outlined in the information sheet.	Yes / No

Please write and sign your name and insert today's date below.

Your Name**Signature****Date**

Keep one copy of this form for yourself and return the other one to the researcher. Thank you!



Dr Maria Lohan

Senior Lecturer

[REDACTED]
[REDACTED]
[REDACTED]

[DATE]

[SCHOOL ADDRESS]

RE: Research study - Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

Dear Teacher,

I am writing to invite you and your Year 11 pupils to participate in a research study. The overall aim of the research is to examine the acceptability and practicality of using and evaluating a unique and scientifically informed educational resource on the topic of teenage men and unintended pregnancy in post-primary schools in Northern Ireland. The aim of the educational resource is to increase boys' as well as girls' intention to avoid an unintended teenage pregnancy.

The resource was developed by a research team at Queen's University Belfast in collaboration with key stakeholders in Northern Ireland which include the Department of Health, Social Services and Public Safety Northern Ireland, the Public Health Agency Northern Ireland, the Council for Curriculum Education and Assessment Northern Ireland (CCEA) as well as teachers, parents and pupils. It is designed to fit within the Personal Development strand of the Learning for Life and Work curriculum and to be used at Key Stage 4.

We would value your participation in this research, as your contribution would inform a process of generating knowledge about effective sexual health resources for young people in Northern Ireland. I have enclosed an information sheet which provides an overview of the research. A member of my team will contact you within the next week to offer you an opportunity to discuss the study further and see if you are happy to participate.

Yours sincerely,



Dr Maria Lohan



Queen's University
Belfast

Information about the Research RSE Teachers

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

We would like to invite you and all of your Year 11 pupils to take part in a research study. Before you decide whether you wish to participate, you should understand why the research is being done, and what it would involve for you and your pupils. Please take time to read the following information carefully.

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What is the purpose of the study?

Teenage women who have an unplanned pregnancy face serious emotional and practical problems as well as risks to their health. Young men's health and wellbeing can also be affected by teenage pregnancy and young men have an important role to play in preventing unintended pregnancy. The overall aim of this study is to test the acceptability and practicality of introducing an educational resource which is designed to help teenage boys as well as girls avoid an unintended pregnancy.

What is the educational resource?

The resource is designed for use at Key Stage 4 within the *Personal Development* strand of the *Learning for Life and Work* curriculum and has been developed in close consultation with health and education experts (including the Public Health Agency Northern Ireland and the Council for Curriculum Education and Assessment Northern Ireland [CCEA]) as well as teachers, parents and pupils. It includes the following components:

- xiv. An interactive film about a 16-year old boy who has just found out that his girlfriend is unexpectedly pregnant;

- xv. Classroom materials for teachers containing four detailed lesson plans with specific classroom-based and homework activities which include group discussions, role-plays, worksheets, and a parent-pupil exercise;
- xvi. 60-minute face-to-face training session for teachers wishing to implement the intervention delivered by a researcher;
- xvii. 60-minute information and discussion session for parents/guardians delivered by RSE teachers; and
- xviii. Detailed information brochures and factsheets about the resource and unintended teenage pregnancy in general for schools, teachers, pupils and parents.

We wish to emphasise and reassure you that the content of the resource and questionnaires being used in the research do not contain any material that is sexually explicit. The focus is on educating young people about unintended teenage pregnancy with a particular emphasis on the roles and responsibilities of teenage men in relation to this.

Why have I been invited?

We are asking seven post-primary schools in Northern Ireland to participate in the research. We are aiming to recruit a mix of schools in terms of management type and location. You are being invited to participate because you are responsible for teaching RSE to Year 11 pupils.

Do I have to take part?

No. It is up to you, your pupils and their parents to decide. If you decide after having read this information sheet that you would prefer not to take part in this research, you can indicate this to the research team and no further action will be taken. If, however, you are happy to hear more about the study a researcher will be happy to provide you with more information (via telephone or a face-to-face meeting at your school).

If after speaking with the researcher you decide you are happy to take part in the research, we will provide similar information sheets and consent forms for pupils and parents. In order for individual pupils to participate they will need to complete a consent form indicating their willingness to take part. Pupils can decide not to take part and do not have to give a reason for saying no. Additionally, parents/guardians will be provided with information about the research and requested to return a form to the research team if they wish for their child to opt-out of the research. Pupils whose parents wish them to opt-out of the research will not participate.

What if my pupils or their parents/guardians decide to withdraw from the study?

Pupils are free to withdraw at any time, without giving a reason. If this happens we will not use the data we have collected from them.

What will we be asked to do if we take part?

Different participants will be asked to do different things:

Schools: Of the 7 recruited schools, 4 will be randomly assigned to the 'intervention group' and 3 will be randomly assigned to the 'comparison group'. Teachers in the intervention group schools will be asked to use the educational resource during four weekly RSE lessons and those in the comparison group will continue with normal RSE practice. At the end of the study we will compare the results of questionnaires completed by pupils in the two groups to see if it is possible to measure the impact of the educational resource on pupils' knowledge, communication skills, intentions to avoid teenage pregnancy and sexual risk-taking behaviour.

Principals and Heads of Year 11: Principals and/or Heads of Year 11 in all schools will be asked to take part in an interview with a researcher about current RSE practice in the school and experiences of taking part in the research. This would take a maximum of 60 minutes.

Year 11 RSE Teachers: Teachers in *intervention group schools* will be provided with a 60-minute training session regarding the use of the resource and facilitation of parents' information and discussion session. They will then be asked to deliver the resource to Year 11 pupils during four consecutive RSE lessons. They will also be asked to facilitate a 60-minute parents' information and discussion session and to be in the room when a researcher delivers the questionnaires to pupils during an RSE lesson (3 times over a 12 month period). Finally, teachers will be asked to take part in an interview with a researcher (max 60-minutes) regarding the acceptability and feasibility of the resource and participation in the research. In total this requires 6.5 hours of a teacher's time over a 12-month period (not including lesson preparation time).

Teachers in *comparison group schools* will be asked to be in the room when a researcher delivers the questionnaires to pupils (3 times over a 12 month period) and take part in an interview with a researcher (max 60-minutes) regarding the acceptability and feasibility of participation in the research. This would require 2.5 hours of the teachers' time over a 12-month period.

Year 11 Pupils: All Year 11 pupils in all 7 schools will complete the same questionnaire on three occasions over a 12-month period (at the beginning of the research and 5 and 9 months later).

Pupils in *intervention group schools* will receive the educational resource during four consecutive RSE lessons. Approximately 5-8 pupils from each Year 11 class will be

asked to take part in a 30 minute focus group discussion with a researcher regarding the acceptability and feasibility of the resource and participation in the research.

In addition to completing the questionnaire on three occasions over a 12-month period, a sample of pupils in *comparison group schools* (two groups of 5-8) will be asked to take part in a 30 minute focus group discussion with a researcher regarding the acceptability of the questionnaire.

Parents of Year 11 Pupils: All parents of pupils in *intervention group schools* will be invited to participate in a 60-minute parents' information and discussion session at the school facilitated by an RSE teacher. The session will include information about the resource and discussion around how best to talk to teenagers about avoiding unintended pregnancy. A sample of these parents (approximately 5 -8) will be invited to take part in a group discussion with the researcher regarding the acceptability and feasibility of the resource and the discussion session. Parents will also be asked to participate in a short homework exercise with their child as part of the intervention in which they answer their child's questions about their views on teenage pregnancy. Following this homework exercise they will be sent a link to a very short online survey regarding their experiences of this and (if appropriate) their experiences of the parents/guardians' information and discussion session.

Parents of pupils in *comparison group schools* will not be invited to participate in the research.

Administration staff: In order to maintain participant confidentiality, administration staff in all 7 schools will be asked to address and post envelopes containing information sheets and opt-out forms for the parents of Year 11 pupils. Administrators in *intervention group schools* will send a second letter or email to parents of Year 11 pupils inviting them to a parents' information and discussion session and a third letter or email to parents with a request for them to complete a short online survey. Administration staff will be asked to record time and resources spent on these activities and we will reimburse all expenses.

The timetable below summarises what participants in intervention and comparison group schools will be asked to do during the study. *Please note: in line with best practice recommendations, schools will not be randomly assigned to intervention or comparison groups until after pupils have completed the questionnaire for the first time.*

Research Timetable

DATE	INTERVENTION SCHOOLS	COMPARISON SCHOOLS
May 2014	Principal/RSE teachers consent to participate	Principal/RSE teachers consent to participate
Sept – Oct 2014	Parents sent information about the	Parents sent information about the

	research	research
Dec 2014	<p>Pupils consent to participate & complete questionnaire during 1 RSE lesson</p> <p>School notified of allocation to intervention group</p> <p>Principal or Head of Year 11 interview <i>(current RSE practice in school)</i></p>	<p>Pupils consent to participate & complete questionnaire during 1 RSE lesson</p> <p>School notified of allocation to comparison group</p>
Jan – Feb 2015	<p>60 minute teacher training session</p> <p>Teacher delivers resource over 4 consecutive RSE lessons</p> <p>Teacher delivers parents' information session</p> <p>Researcher observes one RSE lesson and one parents' information session in each school</p>	
Mar - 2015	<p>Focus groups pupils, focus groups parents and interviews RSE teachers <i>(acceptability and feasibility of the resource)</i></p>	
June 2015	<p>Pupils complete questionnaire during 1 RSE lesson</p>	<p>Pupils complete questionnaire during 1 RSE lesson</p>
Sept - Oct 2015	<p>Pupils complete questionnaire during 1 RSE lesson</p> <p>interviews with RSE teachers <i>(acceptability and feasibility of participation in research)</i></p>	<p>Pupils complete questionnaire during 1 RSE lesson</p> <p>Focus groups with pupils <i>(acceptability of questionnaire)</i></p> <p>Interviews teachers or principals <i>(acceptability of participation in research and current RSE provision)</i></p>

What are the benefits of taking part?

The research would provide you and your pupils with an opportunity to be involved in the evaluation of an innovative relationship and sexuality education resource that is designed to decrease unintended teenage pregnancy. The findings will be widely shared and should help to inform future policy and practice regarding pregnancy education for young people in Northern Ireland.

What if there is a problem?

If you or your pupils are unhappy with anything that happens during the study they can talk to the researchers. If an issue is brought to the attention of the researchers, we will deal with it immediately. If pupils show any signs of visible distress, we will inform the school counsellor. Participants can also make a formal complaint if they wish (details of how to do this are set out at the end of this document).

Will our taking part in the study be kept confidential?

All information gathered during the course of the research will be kept strictly confidential unless child protection, illegal or professional misconduct issues arise. If anything is disclosed during the course of the research that suggests that an individual is involved in or at risk of harmful or criminal activity the researcher will be obliged to pass this information on to the relevant authorities.

Only the researchers will have access to the data. We will follow ethical and legal guidelines and keep all information privately and securely. Your pupils will not be asked to put their names or the name of the school on the questionnaire. We will store the questionnaires and all other paper data in a locked filing cabinet in a secure building at Queen's University Belfast. Names of individuals or schools stored on a computer will be password protected and deleted at the end of the study. Paper data will be destroyed securely five years after the study ends. We will listen to the tapes of the focus group interviews and write down what is said. We will not write down names or anything else that would identify any individual or school.

At the end of the study, all data resulting from the research (including the tapes and transcripts) will be stored for a minimum of 5 years and a maximum of 10 years in Queen's University Belfast. All data will be archived by year 10 in The UK Data Archive (UKDA) located in the University of Essex. This is a centre that specialises in keeping data securely so that other researchers can apply for ethical permission to use it in their own research.

What will happen to the results of the research study?

The results of the study will be published in research reports and in scientific journals. We will not publish anything that could be used to identify you, your pupils or the

school. We will send copies of reports and journal articles to your school so that participants can read them if they want to.

Who has reviewed the study?

All research is looked at by independent group of people, called a Research Ethics Committee, to protect all participants' safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Research Ethics Committee of the School of Nursing and Midwifery, Queen's University Belfast.

Further information and contact details

If you would like further information about the research, please contact Dr Áine Aventin or Dr Maria Lohan.

Dr Áine Aventin
Research Fellow

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Dr Maria Lohan
Senior Lecturer

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

What if I want to make a complaint?

If you and/or your staff or pupils are unhappy with any part of the study and do not wish to approach the research team, please contact:

Dr Oliver Perra,
Chair of the Research Ethics Committee,

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]



Consent Form

RSE Teachers

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

	Please circle answer
1. I have read and understood the information sheet dated (version).	Yes / No
2. I understand what the research is about.	Yes / No
3. I understand that my participation is entirely voluntary and that I am free to withdraw at any time without giving a reason.	Yes / No
4. I understand that relevant sections of data collected during the study may be looked at by responsible individuals from the research team, and that information gathered will be stored securely, coded anonymously and presented in aggregate form so that no individual or organisation is recognisable.	Yes / No
5. I understand that all information gathered during the course of the research will be kept strictly confidential unless child protection, illegal or professional misconduct issues arise. If anything is disclosed during the course of the research that suggests that an individual is involved in or at risk of harmful or criminal activity the researcher will be obliged to pass this information on to the relevant authorities.	Yes / No
6. I understand that the school will be randomly assigned to the intervention group or comparison group after baseline data collection and that only schools in the intervention group will use the educational resource.	Yes / No
7. I agree to take part in the study according to the conditions outlined in the information sheet.	Yes / No

Please write and sign your name and insert today's date below.

Your Name

Signature

Date

Keep one copy of this form for yourself and return the other one to the researcher. Thank you!



Information about the Research (Interview)

RSE Teachers Intervention Group

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

You have already been a participant in the first part of this research by delivering the *If I Were Jack* resource. Thank you for your time and cooperation in this stage of the research. You are now invited to take part in an interview about your experiences of using the resource and taking part in the research. You will be again asked to give your consent to participate and offered the chance to withdraw without giving a reason. Please take time to read the following information carefully.

A reminder of what the study is about

Teenage women who have an unplanned pregnancy face serious emotional and practical problems as well as risks to their health. Young men's health and wellbeing can also be affected by teenage pregnancy and young men have an important role to play in preventing unintended pregnancy. The overall aim of this study is to test the acceptability and practicality of introducing an educational resource which is designed to help teenage boys as well as girls avoid an unintended pregnancy.

Do I have to take part?

It is up to you to decide. We will describe what is involved and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. We will give you a copy of the consent form to keep. You can decide not to take part and you do not have to give a reason for saying no.

What if I decide to withdraw from the study?

You are free to withdraw at any time, without giving a reason. If you do withdraw we will not use the data we have collected from you.

What will I be asked to do if I take part?

You will be asked to take part in an interview with a researcher at a time that is convenient for you. The interview will last between 30-60 minutes and will focus on your experiences of using the *If I Were Jack* resource and taking part in the research. The interview will be tape recorded.

Will my taking part in the study be kept confidential?

All information gathered during the course of the research will be kept strictly confidential unless child protection, illegal or professional misconduct issues arise. If anything is disclosed during the course of the research that suggests that an individual is involved in or at risk of harmful or criminal activity the researcher will be obliged to pass this information on to the relevant authorities.

Only the researchers will have access to the data. We will follow ethical and legal guidelines and keep all information privately and securely. Your pupils will not be asked to put their names or the name of the school on the questionnaire. We will store the questionnaires and all other paper data in a locked filing cabinet in a secure building at Queen's University Belfast. Names of individuals or schools stored on a computer will be password protected and deleted at the end of the study. Paper data will be destroyed securely five years after the study ends. We will listen to the tapes of the focus group interviews and write down what is said. We will not write down names or anything else that would identify any individual or school.

At the end of the study, all data resulting from the research (including the tapes and transcripts) will be stored for a minimum of 5 years and a maximum of 10 years in Queen's University Belfast. All data will be archived by year 10 in The UK Data Archive (UKDA) located in the University of Essex. This is a centre that specialises in keeping data securely so that other researchers can apply for ethical permission to use it in their own research.

What will happen to the results of the research study?

The results of the study will be published in research reports and in scientific journals. We will not publish anything that could be used to identify you, your pupils or the school. We will send copies of reports and journal articles to your school so that participants can read them if they want to.

Further information and contact details

If you would like further information about the research, please contact Dr Áine Aventin or Dr Maria Lohan.

Dr Áine Aventin
Research Fellow

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Dr Maria Lohan
Senior Lecturer

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

What if I want to make a complaint?

If you and/or your staff or pupils are unhappy with any part of the study and do not wish to approach the research team, please contact:

Dr Oliver Perra,
Chair of the Research Ethics Committee,

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]



Consent Form

(Interview)

RSE Teachers Intervention Group

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

	Please circle answer
1. I have read and understood the information sheet dated (version).	Yes / No
2. I understand what the research is about.	Yes / No
3. I understand that my participation is entirely voluntary and that I am free to withdraw at any time without giving a reason.	Yes / No
4. I understand that relevant sections of data collected during the study may be looked at by responsible individuals from the research team, and that information gathered will be stored securely, coded anonymously and presented in aggregate form so that no individual or organisation is recognisable.	Yes / No
5. I understand that all information gathered during the course of the research will be kept strictly confidential unless child protection, illegal or professional misconduct issues arise. If anything is disclosed during the course of the research that suggests that an individual is involved in or at risk of harmful or criminal activity the researcher will be obliged to pass this information on to the relevant authorities.	Yes / No
6. I agree to take part in the study according to the conditions outlined in the information sheet.	Yes / No

Please write and sign your name and insert today's date below.

Your Name**Signature****Date**

Keep one copy of this form for yourself and return the other one to the researcher. Thank you!



Information about the Research (Interview) RSE Teachers/Principals Comparison Group

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

Your Year 11 pupils have participated in the first part of this research by completing a questionnaire during RSE lessons. Thank you for your time and cooperation in this stage of the research. You are now invited to take part in an interview about your experiences of taking part in the research and current RSE practice in your school. You will be asked to give your consent to participate and offered the chance to withdraw without giving a reason. Please take time to read the following information carefully.

A reminder of what the study is about

Teenage women who have an unplanned pregnancy face serious emotional and practical problems as well as risks to their health. Young men's health and wellbeing can also be affected by teenage pregnancy and young men have an important role to play in preventing unintended pregnancy. The overall aim of this study is to test the acceptability and practicality of introducing an educational resource which is designed to help teenage boys as well as girls avoid an unintended pregnancy.

Do I have to take part?

It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. We will give you a copy of the consent form to keep. You can decide not to take part and you do not have to give a reason for saying no.

What if I decide to withdraw from the study?

You are free to withdraw at any time, without giving a reason. If you do withdraw we will not use the data we have collected from you.

What will I be asked to do if I take part?

You will be asked to take part in an interview with a researcher at a time that is convenient for you. The interview will last between 30-60 minutes and will focus on

your experiences of taking part in the research and current RSE practice in your school. The interview will be tape recorded.

Will my taking part in the study be kept confidential?

All information gathered during the course of the research will be kept strictly confidential unless child protection, illegal or professional misconduct issues arise. If anything is disclosed during the course of the research that suggests that an individual is involved in or at risk of harmful or criminal activity the researcher will be obliged to pass this information on to the relevant authorities.

Only the researchers will have access to the data. We will follow ethical and legal guidelines and keep all information privately and securely. Your pupils will not be asked to put their names or the name of the school on the questionnaire. We will store the questionnaires and all other paper data in a locked filing cabinet in a secure building at Queen's University Belfast. Names of individuals or schools stored on a computer will be password protected and deleted at the end of the study. Paper data will be destroyed securely five years after the study ends. We will listen to the tapes of the focus group interviews and write down what is said. We will not write down names or anything else that would identify any individual or school.

At the end of the study, all data resulting from the research (including the tapes and transcripts) will be stored for a minimum of 5 years and a maximum of 10 years in Queen's University Belfast. All data will be archived by year 10 in The UK Data Archive (UKDA) located in the University of Essex. This is a centre that specialises in keeping data securely so that other researchers can apply for ethical permission to use it in their own research.

What will happen to the results of the research study?

The results of the study will be published in research reports and in scientific journals. We will not publish anything that could be used to identify you, your pupils or the school. We will send copies of reports and journal articles to your school so that participants can read them if they want to.

Further information and contact details

If you would like further information about the research, please contact Dr Áine Aventin or Dr Maria Lohan.

Dr Áine Aventin
Research Fellow

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Dr Maria Lohan
Senior Lecturer

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

What if I want to make a complaint?

If you and/or your staff or pupils are unhappy with any part of the study and do not wish to approach the research team, please contact:

Dr Oliver Perra,
Chair of the Research Ethics Committee,

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]



Consent Form

(Interview)

RSE Teachers/Principals Comparison Group

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

	Please circle answer
1. I have read and understood the information sheet dated (version).	Yes / No
2. I understand what the research is about.	Yes / No
3. I understand that my participation is entirely voluntary and that I am free to withdraw at any time without giving a reason.	Yes / No
4. I understand that relevant sections of data collected during the study may be looked at by responsible individuals from the research team, and that information gathered will be stored securely, coded anonymously and presented in aggregate form so that no individual or organisation is recognisable.	Yes / No
5. I understand that all information gathered during the course of the research will be kept strictly confidential unless child protection, illegal or professional misconduct issues arise. If anything is disclosed during the course of the research that suggests that an individual is involved in or at risk of harmful or criminal activity the researcher will be obliged to pass this information on to the relevant authorities.	Yes / No
6. I agree to take part in the study according to the conditions outlined in the information sheet.	Yes / No

Please write and sign your name and insert today's date below.

Your Name

Signature

Date

Keep one copy of this form for yourself and return the other one to the researcher. Thank you!



Queen's University
Belfast

Information about the Research (Interview) Principals/Heads of Year 11 Intervention Group

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

As part of the above research study you are invited to take part in an interview about current RSE practice in your school. You will be asked to give your consent to participate and offered the chance to withdraw without giving a reason. Please take time to read the following information carefully.

A reminder of what the study is about

Teenage women who have an unplanned pregnancy face serious emotional and practical problems as well as risks to their health. Young men's health and wellbeing can also be affected by teenage pregnancy and young men have an important role to play in preventing unintended pregnancy. The overall aim of this study is to test the acceptability and practicality of introducing an educational resource which is designed to help teenage boys as well as girls avoid an unintended pregnancy. As part of this process we would like to collect information about current RSE practice in each participating school.

Do I have to take part?

It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. We will give you a copy of the consent form to keep. You can decide not to take part and you do not have to give a reason for saying no.

What if I decide to withdraw from the study?

You are free to withdraw at any time, without giving a reason. If you do withdraw we will not use the data we have collected from you.

What will I be asked to do if I take part?

You will be asked to take part in an interview with a researcher at a time that is convenient for you. The interview will last between 30-60 minutes and will focus on current RSE practice in your school. The interview will be tape recorded.

Will my taking part in the study be kept confidential?

All information gathered during the course of the research will be kept strictly confidential unless child protection, illegal or professional misconduct issues arise. If anything is disclosed during the course of the research that suggests that an individual is involved in or at risk of harmful or criminal activity the researcher will be obliged to pass this information on to the relevant authorities.

Only the researchers will have access to the data. We will follow ethical and legal guidelines and keep all information privately and securely. Your pupils will not be asked to put their names or the name of the school on the questionnaire. We will store the questionnaires and all other paper data in a locked filing cabinet in a secure building at Queen's University Belfast. Names of individuals or schools stored on a computer will be password protected and deleted at the end of the study. Paper data will be destroyed securely five years after the study ends. We will listen to the tapes of the focus group interviews and write down what is said. We will not write down names or anything else that would identify any individual or school.

At the end of the study, all data resulting from the research (including the tapes and transcripts) will be stored for a minimum of 5 years and a maximum of 10 years in Queen's University Belfast. All data will be archived by year 10 in The UK Data Archive (UKDA) located in the University of Essex. This is a centre that specialises in keeping data securely so that other researchers can apply for ethical permission to use it in their own research.

What will happen to the results of the research study?

The results of the study will be published in research reports and in scientific journals. We will not publish anything that could be used to identify you, your pupils or the school. We will send copies of reports and journal articles to your school so that participants can read them if they want to.

Further information and contact details

If you would like further information about the research, please contact Dr Áine Aventin or Dr Maria Lohan.

Dr Áine Aventin
Research Fellow

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Dr Maria Lohan
Senior Lecturer

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

What if I want to make a complaint?

If you and/or your staff or pupils are unhappy with any part of the study and do not wish to approach the research team, please contact:

Dr Oliver Perra,
Chair of the Research Ethics Committee,

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]



Consent Form

(Interview)

Principals/Heads of Year 11 Intervention Group

**Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial
of an interactive video-drama based intervention in post-primary schools in
Northern Ireland**

	Please circle answer
1. I have read and understood the information sheet dated (version).	Yes / No
2. I understand what the research is about.	Yes / No
3. I understand that my participation is entirely voluntary and that I am free to withdraw at any time without giving a reason.	Yes / No
4. I understand that relevant sections of data collected during the study may be looked at by responsible individuals from the research team, and that information gathered will be stored securely, coded anonymously and presented in aggregate form so that no individual or organisation is recognisable.	Yes / No
5. I understand that all information gathered during the course of the research will be kept strictly confidential unless child protection, illegal or professional misconduct issues arise. If anything is disclosed during the course of the research that suggests that an individual is involved in or at risk of harmful or criminal activity the researcher will be obliged to pass this information on to the relevant authorities.	Yes / No
6. I agree to take part in the study according to the conditions outlined in the information sheet.	Yes / No

Please write and sign your name and insert today's date below.

Your Name

Date

Signature

Keep one copy of this form for yourself and return the other one to the researcher.

Thank you!

Appendix 2 Data collection instruments

PARENT DOCUMENTS

1. If I were Jack parent/guardian survey
2. Online survey schedule for parents/guardians

PUPIL DOCUMENTS

3. Pupil comment sheet
4. Pupil questionnaire

SCHOOL DOCUMENTS

5. Health economics implementation costs schedule

TEACHER DOCUMENTS

6. Focus group topic guide for pupils – questionnaire development
7. Interview topic guide – intervention group – feasibility study
8. Interview topic guide – comparison group – feasibility study
9. Teacher Resource Use Questionnaire

RESEARCHER DOCUMENTS

10. Field note/observation form

1. IF I WERE JACK PARENT/GUARDIAN SURVEY

Parent/Guardian-Pupil Homework Activity

Instructions: Explain to your parent(s)/guardians(s) (or other trusted adult) that you are learning about teenage pregnancy and its consequences. Tell them that you watched a video called *If I Were Jack* which told the story of a young couple who experienced an unplanned pregnancy. Ask your parent(s) to watch the video (explain that it lasts for 15 minutes) or to read the video script excerpt. When they have finished, start a conversation with them using the questions below. Write their answers in the space provided.

1. What did you think of Jack and Emma's story?
2. If you were Jack (or Emma's) parent what would you say when they told you that Emma was pregnant?

3. What would you advise them to do? Why?



2. Online Survey Schedule (Parents/Guardians)

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

- Impressions of participating in the homework exercise
- Good and bad aspects of the homework exercise
- Is the homework exercise meaningful for girls as well as boys
- (If applicable) Impressions of participating in the parents' discussion and information session
- (If applicable) Good and bad aspects of the parents' discussion and information session
- Thoughts on what might be included on project website for parents

3. Pupil Comment Sheet

So now we've come to the end we would like to ask... How was it taking part in the Jack Trial?

Write below good and bad things about taking part in the research. For example, you might think about things like filling in the questionnaire, the questions we asked, the research team, missing classes so you could take part, the chocolates/sweets and anything else that you can think of.

Thank you!

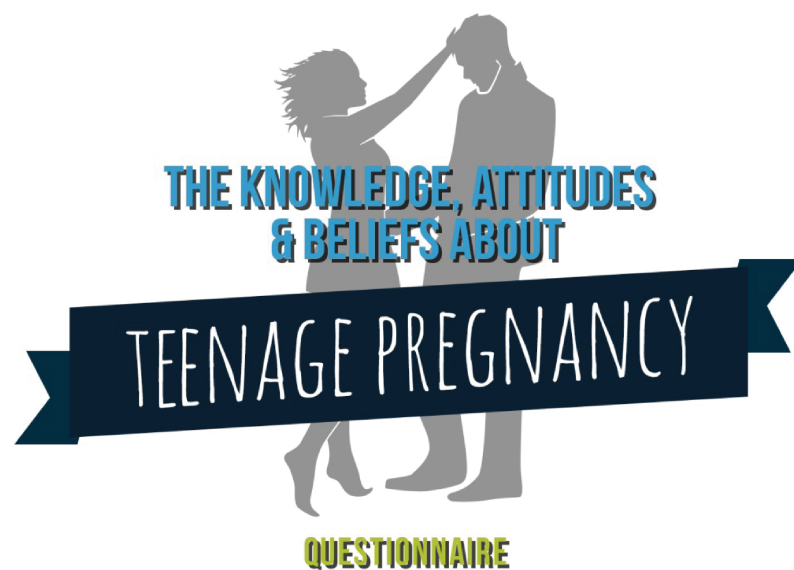


Good things



Bad things

Is there anything that you think we should change the next time we do research like this? Write your thoughts below.



4. Pupil Questionnaire FOLLOW-UP 2

*This project was funded by the National Institute for
Health Research Public Health Research Programme*

(Project number 12/153/26)


**National Institute for
Health Research**

By answering the questions you will help us find out more about teenagers and unintended pregnancy.

Don't worry about getting the answer 'right' or 'wrong'. We just want to know what you think, and something about your experience.

Don't spend much time on any one question; make a choice and move to the next.

Don't ask others how they are answering their questions or how they think you should answer yours.

Young people do sexual things at different ages.

Many of you may not have had any sexual experiences.

We are interested in your ideas and experiences whatever they are, so please answer these questions as fully and honestly as possible.

You can skip any questions that you do not feel comfortable answering!

If there are any questions you don't understand, look at the list of definitions at the end of the questionnaire but please ask us if you need any help.

YOUR ANSWERS ARE CONFIDENTIAL

So, please be honest about how you feel and what you think!

PLEASE NOTE: As the questionnaire is confidential, we will not be able to trace it back to you. Therefore, if you write in the questionnaire about something that is upsetting or worrying you or someone else we will not be able to do anything about it or help you in any way because we won't know who filled in the questionnaire. If anything is worrying you, you should speak to your parents/guardians or teacher or you can contact Child Line free on **0800 1111**

ABOUT YOURSELF

1.	Are you...	(Tick one)	<input type="checkbox"/> Male	<input type="checkbox"/> Female
	<input checked="" type="checkbox"/>			

2.	What is your date of birth?	D	D	/	M	M	/	Y	Y	Y	Y

3.	Do you know your postcode?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	If yes, your postcode is...	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
	An example is	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
	Another example	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	

4.	What do you think you will be doing when you leave school?	(Tick one)	
		<input checked="" type="checkbox"/>	
		<input type="checkbox"/>	At college or university full-time
		<input type="checkbox"/>	At college or university part-time and working
		<input type="checkbox"/>	Working full-time
		<input type="checkbox"/>	Working part-time
		<input type="checkbox"/>	On a training scheme
		<input type="checkbox"/>	Unemployed – <i>Go to Question 4a</i>
		<input type="checkbox"/>	Other – <i>Go to Question 4b</i>
4a	Write in why you think you will be unemployed:		<hr/>
4b	If other, please write in...		<hr/>

5.	Have you felt sexually attracted...	(Tick one)	
		<input checked="" type="checkbox"/>	
		<input type="checkbox"/>	Only to females, never to males
		<input type="checkbox"/>	More often to females, and at least once to males

	<input type="checkbox"/> About equally often to females and to males <input type="checkbox"/> More often to males, and at least once to females <input type="checkbox"/> Only to males, and never to females <input type="checkbox"/> I have never felt sexually attracted to anyone
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ABOUT YOUR FAMILY

In the following section the term 'parents' includes adoptive parents

6.	Who are you currently living with? (Tick one) [✓] If more than one category applies. Please pick the one that you spend <u>the most</u> time with. <input type="checkbox"/> Both parents in same household <input type="checkbox"/> Mother only <input type="checkbox"/> Father only <input type="checkbox"/> Mother and Partner or Step Father <input type="checkbox"/> Father and Partner or Step Mother <input type="checkbox"/> Grandparents only <input type="checkbox"/> Foster care <input type="checkbox"/> Residential care <input type="checkbox"/> Others If others please write in... _____
7.	How well off do you think your family is financially? (By this we mean how well-off your family is in terms of money) (Tick one) [✓] <input type="checkbox"/> Very well off <input type="checkbox"/> Well off <input type="checkbox"/> Average <input type="checkbox"/> Not very well off <input type="checkbox"/> Not at all well off

	<input type="checkbox"/> Don't Know
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8.	Do you get free school meals? (Tick one) <input checked="" type="checkbox"/> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know
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9.	How would you describe your parents / guardians? My parents / guardians... <i>(Tick one box per line)</i> <input checked="" type="checkbox"/> <table> <tr> <th></th> <th>Strongly Agree</th> <th>Agree</th> <th>Unsure</th> <th>Disagree</th> <th>Strongly Disagree</th> </tr> <tr> <td>sense when I'm upset about something</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>try to control everything I do</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>encourage me to talk about my difficulties</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>treat me like a baby</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table>		Strongly Agree	Agree	Unsure	Disagree	Strongly Disagree	sense when I'm upset about something	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	try to control everything I do	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	encourage me to talk about my difficulties	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	treat me like a baby	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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MORE ABOUT YOU

In questions that follow: **‘sex’** and **‘penetrative sex’** and **‘sexual intercourse’** all mean:
a man putting his penis into a woman’s vagina or **‘going the whole way’**

‘Contraception’ means using artificial ways of avoiding pregnancy.

‘Condoms’ or **‘the pill’** are both examples of contraception.

‘Unintended pregnancy’ is a pregnancy that is not planned, not expected,
and not wanted at that time.

10.

When thinking about future sexual encounters over the new few months or years, how likely is it that you would...

(Tick one box per line) [✓]

	Extremel y likely	Somewhat likely	Not Sure	Somewhat unlikely	Extremel y unlikely
Be able to get contraceptives	[]	[]	[]	[]	[]
Feel OK about saying no if you did not want to have sex	[]	[]	[]	[]	[]
Talk to your parents about avoiding an unintended pregnancy	[]	[]	[]	[]	[]
Know where to get advice about contraception	[]	[]	[]	[]	[]
Feel comfortable about carrying condoms	[]	[]	[]	[]	[]
Have sex if you were drunk or high	[]	[]	[]	[]	[]
Think about the consequences of an unintended pregnancy	[]	[]	[]	[]	[]
Say no to sex unless you had contraception	[]	[]	[]	[]	[]
Think about not having sex until you are older	[]	[]	[]	[]	[]
Talk to your partner about using contraception	[]	[]	[]	[]	[]
Share the responsibility for using contraception with your partner	[]	[]	[]	[]	[]
Take into account what your parents might think about you having sex	[]	[]	[]	[]	[]
Take into account what your parents might think about you using contraception	[]	[]	[]	[]	[]
Discuss ways to avoid unintended pregnancy with your partner	[]	[]	[]	[]	[]
Resist the influence of peer pressure to have sex	[]	[]	[]	[]	[]

ALCOHOL & DRUGS

11.

Have you ever taken an alcoholic drink *(Tick one)* [✓]
(not just a taste or a sip)?

	<p><input type="checkbox"/> Yes (<i>Go to Question 12</i>)</p> <p><input type="checkbox"/> No (<i>Go to Question 13</i>)</p>
12.	<p>Since you completed the last questionnaire in June 2015, how often have you got <i>(Tick one)</i> [✓] <u>drunk?</u></p> <p><input type="checkbox"/> Never</p> <p><input type="checkbox"/> Less than once a month</p> <p><input type="checkbox"/> About 2 or 3 times a month</p> <p><input type="checkbox"/> About once a week</p> <p><input type="checkbox"/> More than once a week</p>

13.	<p>Have you ever taken other drugs (not alcohol)?</p> <p style="text-align: right;"><i>(Tick one)</i> [✓]</p> <p style="text-align: right;">[] Yes <i>(Go to Question 14)</i></p> <p style="text-align: right;">[] No <i>(Go to Question 15)</i></p>
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14.	<p>Since you completed the last questionnaire in June 2015, how often have you used the following drugs?</p> <p><i>(Tick one box per line)</i> [✓]</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%;"></th> <th style="width: 10%; text-align: center;">Never</th> <th style="width: 10%; text-align: center;">Less than once a month</th> <th style="width: 10%; text-align: center;">About 2 or 3 times a month</th> <th style="width: 10%; text-align: center;">About once a week</th> <th style="width: 10%; text-align: center;">More than once a week</th> </tr> </thead> <tbody> <tr> <td>Legal highs (e.g. herbals)</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> </tr> <tr> <td>Cannabis</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> </tr> <tr> <td>Other drugs (e.g. ecstasy, magic mushrooms, LSD, cocaine, heroin)</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> </tr> </tbody> </table>		Never	Less than once a month	About 2 or 3 times a month	About once a week	More than once a week	Legal highs (e.g. herbals)	[]	[]	[]	[]	[]	Cannabis	[]	[]	[]	[]	[]	Other drugs (e.g. ecstasy, magic mushrooms, LSD, cocaine, heroin)	[]	[]	[]	[]	[]
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KNOWLEDGE

15.	<p>Do you think the following statements are ‘true’ or ‘false’? If you don’t know that answer tick ‘not sure’.</p> <p><i>(Tick one box per line)</i> [✓]</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%;"></th> <th style="width: 15%; text-align: center;">True</th> <th style="width: 15%; text-align: center;">False</th> <th style="width: 20%; text-align: center;">Not Sure</th> </tr> </thead> <tbody> <tr> <td>Washing the vagina after penetrative sex will help to prevent pregnancy.</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> </tr> <tr> <td>A girl <u>can</u> get pregnant even if the boy withdraws his penis (pulls out) before ejaculation (coming).</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> </tr> <tr> <td>Contraception (when used correctly) provides as much protection against pregnancy as not having sex.</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> </tr> <tr> <td>The rhythm method (only having sex during the few days before and after a woman’s period) is as safe as using a condom in preventing pregnancy.</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> </tr> <tr> <td>When teenagers have penetrative sex <u>for the first time</u>, most of them use condoms.</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> </tr> <tr> <td>Teenage men can seek advice from pregnancy counsellors.</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> </tr> <tr> <td>More than half of all teenagers in Northern Ireland have had penetrative sex by the time they are 16.</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> </tr> </tbody> </table>		True	False	Not Sure	Washing the vagina after penetrative sex will help to prevent pregnancy.	[]	[]	[]	A girl <u>can</u> get pregnant even if the boy withdraws his penis (pulls out) before ejaculation (coming).	[]	[]	[]	Contraception (when used correctly) provides as much protection against pregnancy as not having sex.	[]	[]	[]	The rhythm method (only having sex during the few days before and after a woman’s period) is as safe as using a condom in preventing pregnancy.	[]	[]	[]	When teenagers have penetrative sex <u>for the first time</u> , most of them use condoms.	[]	[]	[]	Teenage men can seek advice from pregnancy counsellors.	[]	[]	[]	More than half of all teenagers in Northern Ireland have had penetrative sex by the time they are 16.	[]	[]	[]
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16.	<p>What is the legal age of consent (the age at which you can legally first have sex) in Northern Ireland?</p> <p>Write in... _____ years</p>
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17.	<p>Can you think of any health services, clinics or places you could visit if you wanted to get the following?</p>
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Free Contraception	(Write _____ in)
Advice on sexual health (e.g. pregnancy, sexually transmitted infections)	(Write _____ in)

18.	Can you think of any websites which provide information on sexual health, relationships and pregnancy?
	(Write in) _____

ATTITUDES & BELIEFS

In the following section a **‘sexual partner’** means someone you have had penetrative sex with and a **‘potential partner’** means someone who you might consider having penetrative sex with in the future.

19.	<p>Whose responsibility is it to prevent unintended pregnancy?</p> <p>Put an X on the line below to show how much responsibility you think boys and girls should have. For example, if you think girls should have more responsibility than boys, put an X on the line closer to girl; if you think boys should have more responsibility than girls, put an X on the line closer to boy; If you think boys and girls should have equal responsibility, put an X in the middle of the line.</p> <div style="display: flex; align-items: center; justify-content: space-between;"> <div style="text-align: center;"> <p>100%</p> <p>Boy</p> </div> <div style="flex-grow: 1; border-top: 1px solid black; position: relative;"> <div style="position: absolute; left: 0; right: 0; top: -10px; border-bottom: 1px solid black; height: 10px;"></div> <div style="position: absolute; left: 0; right: 0; top: 10px; border-bottom: 1px solid black; height: 10px;"></div> </div> <div style="text-align: center;"> <p>100%</p> <p>Girl</p> </div> </div>
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20.	<p>In this section, we want to know how comfortable or uncomfortable you are doing different things. Being “uncomfortable” means it is difficult for you and makes you nervous and uptight. For each item, tick the box that describes you best.</p> <p>How comfortable are you...</p> <p><i>(Tick one box per line)</i> [✓]</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%;"></th> <th style="width: 12.5%; text-align: center;">Comfortable</th> <th style="width: 12.5%; text-align: center;">A little Uncomfortable</th> <th style="width: 12.5%; text-align: center;">Somewhat Uncomfortable</th> <th style="width: 12.5%; text-align: center;">Very Uncomfortable</th> </tr> </thead> <tbody> <tr style="background-color: #e0f2f7;"> <td>IF YOU ARE A GIRL: Talking with a boyfriend about avoiding pregnancy</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> </tr> <tr> <td>IF YOU ARE A BOY: Talking with a girlfriend about avoiding pregnancy</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> </tr> <tr style="background-color: #e0f2f7;"> <td>GIRLS & BOYS: Talking with parents about avoiding pregnancy</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> <td style="text-align: center;">[]</td> </tr> </tbody> </table>		Comfortable	A little Uncomfortable	Somewhat Uncomfortable	Very Uncomfortable	IF YOU ARE A GIRL: Talking with a boyfriend about avoiding pregnancy	[]	[]	[]	[]	IF YOU ARE A BOY: Talking with a girlfriend about avoiding pregnancy	[]	[]	[]	[]	GIRLS & BOYS: Talking with parents about avoiding pregnancy	[]	[]	[]	[]
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21.	<p>In this section, please indicate whether or not you feel like you could do each activity. Mark "Yes" if you feel like you could do the activity and "No" if you feel like you couldn't do the activity. For those activities that you answer "Yes" to, rate your degree of confidence in your ability to do the activity on the scale.</p> <table border="1"> <thead> <tr> <th rowspan="2"></th><th colspan="2">Could you do it?</th><th colspan="5">IF YES, how certain are you that you could do it?</th></tr> <tr> <th>Yes</th><th>No</th><th>Very Uncertain</th><th>Somewhat Uncertain</th><th>Neither Certain nor Uncertain</th><th>Somewhat Certain</th><th>Very Certain</th></tr> </thead> <tbody> <tr> <td>Refuse a sexual advance by your partner.</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr> <td>Have a sexual encounter without feeling you have to have penetrative sex.</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr> <td>Discuss using condoms and/or other contraceptives with a sexual partner.</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr> <td>Ask a sexual partner to wait to have penetrative sex if contraception is not available at the time.</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr> <td>Carry condoms around with you "just in case".</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> </tbody> </table>						Could you do it?		IF YES, how certain are you that you could do it?					Yes	No	Very Uncertain	Somewhat Uncertain	Neither Certain nor Uncertain	Somewhat Certain	Very Certain	Refuse a sexual advance by your partner.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Have a sexual encounter without feeling you have to have penetrative sex.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Discuss using condoms and/or other contraceptives with a sexual partner.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Ask a sexual partner to wait to have penetrative sex if contraception is not available at the time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Carry condoms around with you "just in case".	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Control your sex urges while under the influence of alcohol or drugs.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Choose when and with whom to have sex.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Refuse to do something sexually which you don't feel comfortable about.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Be able to get condoms/contraceptives.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Discuss contraception with a doctor or health professional.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Admit being sexually inexperienced to your sexually experienced peers.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reject an unwanted sexual advance from someone other than your boyfriend/girlfriend.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reject an unwanted sexual advance from someone if you were under the influence of drugs or alcohol.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Choose to delay sex until you are older.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

22. Please mark the box that matches your opinion about these statements concerning a man's role. Mark one box only for each question.

(Tick one box per line) [✓]	Strongly Disagree	Disagree	Agree	Strongly Agree
It is essential for a guy to get respect from others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A man always deserves the respect of his wife/partner and children.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

I admire a guy who is totally sure of himself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A guy will lose respect if he talks about his problems.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A young man should be physically tough, even if he is not big.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
It bothers me when a boy acts like a girl.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I don't think that a husband/partner should have to do housework.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Men are always ready for sex.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

23. Read the statements below and choose the response that best describes your degree of agreement/disagreement with each statement. Tick only one response for each statement.

(Tick one box per line) ☒ Strongly Agree Agree Undecided Disagree Strongly Disagree

My mother would feel okay about me having sex with many different people.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am uncomfortable around people who spend much of their time talking about their sexual experiences.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
My father would feel upset if he thought I was having sex with many different people.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Among my friends, men who have the most sexual experience are the most popular.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
My friends disapprove of being involved with someone who is known to be sexually 'easy'.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
According to my parents, having sexual intercourse is an important part of my becoming an adult.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Most of my friends don't approve of having multiple sexual partners.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
My friends and I enjoy telling each other about our sexual experiences.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
My parents emphasise that sex and intimacy should always be linked.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Most of my friends believe that you should only have sex in a serious relationship.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Among my friends alcohol is used to get people to have penetrative sex with you.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	My parents would disapprove of my being sexually active.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23.	Read the statements below and choose the response that best describes how you feel about each statement. Tick only one response for each statement.					
	(Tick one box per line) [✓]	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
	My friends approve of being involved with someone just for sex.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	My friends brag about their sexual exploits.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	My friends suggest sexual partners to each other who are known to be sexually easy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	My parents encourage me to have sex with many people before I get married.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Among my friends, people seldom discuss their sexuality.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Among my friends, women who have the most sexual experience are the most popular.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	My father would feel okay about my having casual sexual encounters.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	My mother would only approve of me having sex in a serious relationship.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	My parents never say anything about sex.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

BEHAVIOUR

24.	Have you ever experienced penetrative sex (penis-vagina) with another person?
	(Tick one) [✓]
	<input type="checkbox"/> Yes (Go to Question 25)
	<input type="checkbox"/> No (Go to Question 43)
25.	If yes, what age were you the FIRST time?
	Write in... _____ years
26.	How many people have you had penetrative sex (penis-vagina) with EVER?
	(Tick one) [✓]
	<input type="checkbox"/> One

	<input type="checkbox"/> Between 2 and 5 <input type="checkbox"/> Between 6 and 10 <input type="checkbox"/> More than 10
27.	<p>Thinking about ALL the times you have had sex EVER. How often were you or your partner protected against pregnancy? (Do not count the withdrawal method or emergency contraception – “the morning after pill”)</p> <p>(Tick one) <input checked="" type="checkbox"/></p> <input type="checkbox"/> Never <input type="checkbox"/> Not very often <input type="checkbox"/> About half the time <input type="checkbox"/> Most of the time <input type="checkbox"/> Always
28.	<p>How many times have you had penetrative sex (penis-vagina) <u>since you completed the last questionnaire in June 2015?</u></p> <p>(Tick one) <input checked="" type="checkbox"/></p> <input type="checkbox"/> Not since June 2015 <input type="checkbox"/> Once <input type="checkbox"/> Between 2 and 5 times <input type="checkbox"/> Between 6 and 10 times <input type="checkbox"/> Between 11 and 20 times <input type="checkbox"/> More than 20 times
29.	<p>When was the last time you had penetrative sex (penis-vagina) with someone?</p> <p>(Tick one) <input checked="" type="checkbox"/></p> <input type="checkbox"/> Less than a week ago <input type="checkbox"/> More than a week but less than a month ago <input type="checkbox"/> 1-4 months ago <input type="checkbox"/> More than 4 months ago
30.	<p>The <u>last time</u> you had penetrative sex, did you or your partner use any form of contraception?</p> <p>(Tick one) <input checked="" type="checkbox"/></p>

	<input type="checkbox"/> None for me, don't know about partner <i>(Go to Question 32)</i>
	<input type="checkbox"/> None for either of us <i>(Go to Question 32)</i>
	<input type="checkbox"/> Yes <i>(Go to Question 31)</i>

31.	<p>If yes, please tick all contraceptives that you used <u>the last time you had sex</u>:</p> <p>(Tick all that apply) [✓]</p> <div> <input type="checkbox"/> The Pill, contraceptive patch, or contraceptive vaginal ring </div> <div> <input type="checkbox"/> Condoms (including female condoms) </div> <div> <input type="checkbox"/> Emergency contraceptive pill (morning after pill) </div> <div> <input type="checkbox"/> Injection </div> <div> <input type="checkbox"/> Contraceptive implant </div> <div> <input type="checkbox"/> Withdrawal method (boy pulls out before coming) </div> <div> <input type="checkbox"/> Intrauterine device (coil/IUD/IUS) </div> <div> <input type="checkbox"/> Diaphragm or cap or spermicide </div> <div> <input type="checkbox"/> Natural family planning (safe period/rhythm method) </div> <div> <input type="checkbox"/> Don't know name of the contraception </div> <div> <input type="checkbox"/> Other </div> <p>If other, please write in name... _____</p>
32.	<p><u>For boys only</u> (girls go to Q33):</p> <p>Have you ever got a girl pregnant?</p> <p>(Tick one) [✓]</p> <div> <input type="checkbox"/> Yes <i>(Go to Question 34)</i> </div> <div> <input type="checkbox"/> No <i>(Go to Question 39)</i> </div> <div> <input type="checkbox"/> Don't know <i>(Go to Question 39)</i> </div>

33.	<p><u>For girls only</u> (boys go to Q34):</p> <p>Have you ever been pregnant?</p> <p>(Tick one) [✓]</p> <div> <input type="checkbox"/> Yes <i>(Go to Question 34)</i> </div> <div> <input type="checkbox"/> No <i>(Go to Question 38)</i> </div> <div> <input type="checkbox"/> Don't know <i>(Go to Question 38)</i> </div>
-----	---

34.	How many months ago did you/she get pregnant?	(Tick one) [✓] <input type="checkbox"/> Less than one month ago <input type="checkbox"/> Between 2 and 5 months ago <input type="checkbox"/> Between 6 and 9 months ago <input type="checkbox"/> Between 10 and 12 months ago <input type="checkbox"/> More than a year ago <input type="checkbox"/> Don't know
35.	What happened with the pregnancy?	(Tick one) [✓] <input type="checkbox"/> Still pregnant <input type="checkbox"/> Miscarriage <input type="checkbox"/> An abortion <input type="checkbox"/> A baby <input type="checkbox"/> Don't know
36.	For girls only (boys go to Q37): Just <u>before</u> I became pregnant...	(Please tick the statement which <u>most</u> applies) <input checked="" type="checkbox"/> [✓] <input type="checkbox"/> I intended to get pregnant <input type="checkbox"/> My intentions kept changing <input type="checkbox"/> I did not intend to get pregnant
37.	For boys only (girls go to Q38): Just <u>before</u> my partner became pregnant...	(Please tick the statement which <u>most</u> applies) <input checked="" type="checkbox"/> [✓] <input type="checkbox"/> I intended for my partner to get pregnant <input type="checkbox"/> My intentions kept changing <input type="checkbox"/> I did not intend for my partner to get pregnant
38.	For girls only: Since June 2015, how many male partners have you had sex with?	(Tick one) [✓] <input type="checkbox"/> One <input type="checkbox"/> Between 2 and 5 <input type="checkbox"/> Between 6 and 10 <input type="checkbox"/> More than 10

39.	<p>For boys only: Since June 2015, how many female partners have you had sex with? (Tick one) [✓]</p> <p><input type="checkbox"/> One</p> <p><input type="checkbox"/> Between 2 and 5</p> <p><input type="checkbox"/> Between 6 and 10</p> <p><input type="checkbox"/> More than 10</p>
40.	<p>Since you completed the last questionnaire in June 2015, how many times have you had penetrative sex (penis-vagina) without a condom? (Tick one) [✓]</p> <p><input type="checkbox"/> Never</p> <p><input type="checkbox"/> Once</p> <p><input type="checkbox"/> Between 2 and 5 times</p> <p><input type="checkbox"/> Between 6 and 10 times</p> <p><input type="checkbox"/> Between 11 and 20 times</p> <p><input type="checkbox"/> More than 20 times</p>
41.	<p>Since June 2015, have you had penetrative sex when you did not want to with a boyfriend, girlfriend or one night stand? (Tick one) [✓]</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>
42.	<p>Since June 2015, have you had any of the following sexually transmitted infections (STIs)? (Tick all that apply) [✓]</p> <p><input type="checkbox"/> Chlamydia</p> <p><input type="checkbox"/> Genital Warts</p> <p><input type="checkbox"/> Herpes</p> <p><input type="checkbox"/> Gonorrhoea</p> <p><input type="checkbox"/> Pubic Lice</p> <p><input type="checkbox"/> Trichomonas (TV)</p> <p><input type="checkbox"/> Syphilis</p> <p><input type="checkbox"/> HIV</p> <p><input type="checkbox"/> Hepatitis</p> <p><input type="checkbox"/> Pelvic Infection (PID)</p> <p><input type="checkbox"/> Vaginal thrush (Candida, Yeast</p>

	<p>Infection)</p> <p><input type="checkbox"/> Can't remember the name</p> <p><input type="checkbox"/> None</p> <p><input type="checkbox"/> Other</p> <p>Other, please write in name... _____</p>																								
43.	<p>Since June 2015, have you chosen to delay sex because...</p> <p><i>(Tick one box per line)</i> <input checked="" type="checkbox"/></p> <table border="1"> <thead> <tr> <th></th><th>Yes</th><th>No</th></tr> </thead> <tbody> <tr> <td>you did not have contraception available in time</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr> <td>your parents would not approve</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr> <td>you were under the influence of alcohol or drugs</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr> <td>you believe you should wait until you are older</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr> <td>it was not the right partner</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> </tbody> </table>		Yes	No	you did not have contraception available in time	<input type="checkbox"/>	<input type="checkbox"/>	your parents would not approve	<input type="checkbox"/>	<input type="checkbox"/>	you were under the influence of alcohol or drugs	<input type="checkbox"/>	<input type="checkbox"/>	you believe you should wait until you are older	<input type="checkbox"/>	<input type="checkbox"/>	it was not the right partner	<input type="checkbox"/>	<input type="checkbox"/>						
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it was not the right partner	<input type="checkbox"/>	<input type="checkbox"/>																							
44.	<p>How easy or difficult would it be for you to:</p> <p><i>(Tick one box per line)</i> <input checked="" type="checkbox"/></p> <table border="1"> <thead> <tr> <th></th><th>Very Easy</th><th>Easy</th><th>Not Sure</th><th>Difficult</th><th>Very Difficult</th></tr> </thead> <tbody> <tr> <td>Get condoms of your own</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr> <td>Suggest using condoms to a partner</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr> <td>Use a condom properly</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> </tbody> </table>		Very Easy	Easy	Not Sure	Difficult	Very Difficult	Get condoms of your own	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Suggest using condoms to a partner	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Use a condom properly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Use a condom properly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																				
45.	<p>How do you feel about the questions you were asked in this questionnaire? Did you feel...</p> <p><i>(Tick one)</i> <input checked="" type="checkbox"/></p> <table border="1"> <tbody> <tr> <td><input type="checkbox"/></td><td>Comfortable answering all the questions</td></tr> <tr> <td><input type="checkbox"/></td><td>Comfortable answering most of the questions</td></tr> <tr> <td><input type="checkbox"/></td><td>Uncomfortable answering most of the questions</td></tr> <tr> <td><input type="checkbox"/></td><td>Uncomfortable answering all the questions</td></tr> </tbody> </table>	<input type="checkbox"/>	Comfortable answering all the questions	<input type="checkbox"/>	Comfortable answering most of the questions	<input type="checkbox"/>	Uncomfortable answering most of the questions	<input type="checkbox"/>	Uncomfortable answering all the questions																
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THANK YOU FOR COMPLETING THIS QUESTIONNAIRE**46. Is there anything else that you'd like to add?**

For example, any comments about the answers that you gave or about this questionnaire?

Here are some definitions of the words we have used in this questionnaire:

Word	Definitions
Sex	Sexual activity, including specifically sexual intercourse (also called going the whole way, sexual intercourse, making love).
Sexual Intercourse	Sexual contact between individuals involving penetration, especially the insertion of a man's erect penis into a woman's vagina (also called going the whole way, intercourse, making love).
Penetrative Sex	Sexual contact between a male and a female involving the insertion of a man's erect penis into a woman's vagina (also called going the whole way, sexual intercourse, making love).
Unintended Pregnancy	A pregnancy that is not planned, not expected and not wanted at that time.
Contraception	Using artificial ways of avoiding pregnancy. Condoms and 'the pill' are both types of contraception.
Condom	A thin rubber sheath worn on a man's penis during sexual intercourse as a contraceptive or as a protection against infection.
The Pill	A pill taken by women which contains hormones that prevent pregnancy.
Sexual Advance	Can be used to describe an attempt by one person to gain sexual favour with another (also called 'come on to' or 'pull').
Sexuality	Can be used to describe a person's sexuality or preference e.g. whether you are sexually attracted to males, females, both males and females, or have never been attracted to anyone.
Sexually Active	Can be used to describe a person who participates in sexual intercourse.
Sexual partner	Someone you have had sexual intercourse with.
Potential Partner	Someone you might consider having sexual intercourse with in the future.
Sexual Encounter	To have sexual intercourse with another person.

Sexual Exploits	The people you've had sexual intercourse with in the past.
Sexually Easy	Can mean someone who agrees to have sexual intercourse with others without difficulty.
Legal High	Substances which produce similar effects to illegal drugs (such as cannabis and ecstasy) but that are not yet controlled under the Misuse of Drugs Act. They cannot be sold for human consumption so they are often sold as bath salts or plant food to get round the law.
Manipulate	To control or influence (a person or situation) cleverly or dishonestly.

ONLY DO THESE IF YOU FINISH EARLY!

Sudoku Easy

Word searches

Sudoku Medium

	9		1			3		
	1			6			2	4
7			3	8				
						4		6
	8	3				1	9	
2		7						
				9	3			5
6	7			2			8	
		9		4		6		

Sudoku Hard

5					2		8	
								6
		7	1			5	3	
	3		7				5	9
		2		4		8		
7	5				9		1	
	9	8			4	3		
1								
	2		8					5

4		5			8		2	
			1					
	2			6	7		9	
		8					3	
5		6				2		1
	1					4		
	8		9	7			6	
					1			
	9		8			5		7

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The first four words
you see describe you.

UUL
LUULAZYSB
NDMQNLMHAPPYF
RWGTGYJDI MPATIENTTG
CGENUINEHELEAGANTCTG
POHECYTPREYPEACEFULCB
CMKCA XUGSLRESERVE DGUQ
MOPBCL TPOMZ WITTYC
CUASEC AFBAY AAOFUA
OHRSRNUY SNNUSENTI MENTALRX
SAASQT LGTMDLZGLOVELYHPDID
IRGEIQRAZUVIKDE PENDENTGSNH
ONMEOGI TSBHNLOY ALNLET HARGIC
MCI ONRC IZBOGOVERDRAMATICRHN
AENUACPN COTALENTEDSVTRGRADL
RGST U GJRCHARI SMATIC PICCA
EQNE OONSTHONESTNU OTEF
DZBFV NAI VEF SHYJZ ELIFX
WDQJO ZIICU
CDKIND YVVTAL
JLKRKV PASSIONATEZ XHEL
INSECURESTHOUGHTFULJ
ELOQUENTJ V WRESTLESS
HEJOUTSPOKENUFT EX
OUTGOINGCNGKL
EGUOSWEET
VLO

Spongebob Characters

Y F O O F P E D C I U D O N
R L S U L H L U N S L D P B
S E Y Q F I B A H B S R Y G
F P L M U L A T O R P A U A
S E P G B L M N D R O W N T
M S L M N U L M K E N D U K
Y X A J I A B I G X G I Y A
S A N D Y S R B A S E U R R
T A K L A A S T L M B Q R E
E Y T B R D G P S E O S A N
R R O O A A S L R B B Y L A
Y S N S R S E O O I J A U S
K C I R T A P P E E S I S E
N M R S P U F F A S T S M S

BUBBLE BASS
SQUIDWARD
PHIL
MISS PRISS
PLANKTON
KAREN
STRANGLER
SQUILLIAM
FOOFY
LARRY
SANDY
UDON
MRS PUFF
SPONGEBOB
PATRICK
JIM
MYSTERY
PABLE
PEARL
REX

5. Implementation Costs Schedule

Item	Description	Note on intervention vs longer term costs
Teaching Staff Training	1. The development of a webinar	
	2. The development of an on-line forum and facebook page on project website	
	3. ¼ day training as part of RSE Teacher Training Day <ul style="list-style-type: none"> including time to train the trainer and time for teachers and teaching release time (RSE training normally funded by Public Health Agency) and/or ¼ day individual training for teachers by researcher 	We will trial both these approaches to teacher training to test feasibility
	4. Downloading and copying of Trainers Guide. 5. Downloading and copying for teachers a single copy of: The Teachers booklet; The Pupil's booklet; The Parents' booklet & Factsheets. 6. A DVD for each.	We have sufficient paper based copies of all of these booklets for the feasibility trial along with copies of the DVD.
School Capital costs (equipment and space) to deliver intervention to pupils	1. A suite of computers to provide each pupil in each participating class (usually about 30 pupils) with an individual PC. 2. Computers with sound facility and individual headphones.	
School Capital costs (equipment and space) to deliver intervention to parents	1. An assembly hall with chairs and OHP. 2. Light refreshments. 3. Copies of the DVD for parents (to take away). 4. Copies of parents' booklets.	We have sufficient copies of booklet and DVD for sessions.
Teaching Materials	1. DVDs for each pupil, 2. Distribution costs of teacher, and pupil booklets and DVDs to schools vs. downloading of web versions of all (DVD and booklets).	We have sufficient DVDs and paper based copies for feasibility trial but we will test

		longer term costs of schools downloading them.
Teaching Time	<ol style="list-style-type: none"> 1. Time to download resources (versus time receive in the post/from researcher). 2. Staff training time (noted above). 3. Time to read/become familiar with lesson plans. 	
School Costs	<ol style="list-style-type: none"> 1. Secretarial time to send information letters to each parent/guardian. 2. Postage of letters to parents 3. Janitor support for parental evening. 	



6. Focus Group Topic Guide

(Questionnaire Study)

Pupils

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

What did you think about the length of the questionnaire?

What did you find useful or interesting about the questionnaire?

What did you find difficult or confusing about the questionnaire?

When you talk about these issues with your friends what terms do you tend to use?

Were the terms used in the questionnaire a fair reflection of how you talk about these issues?
If not, in what ways do they differ?

Did answering the questionnaire make you think differently about unintended pregnancy?

We have tried to include a number of important issues in regard to unintended pregnancy, do you think there are some we have missed?

Is there anything you think should be removed from the questionnaire?



7. Interview Topic Guides

Intervention Group

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

Interviews with Teachers

- The nature, quantity and quality of RSE currently taught in school
- Facilitators and barriers to teaching RSE currently in school
- How the teacher training session was organised
- The quality of the teacher training experience
- How the training session could be improved
- Thoughts on what might be included in a webinar for teacher training
- Impressions and thoughts on the intervention text materials
- What worked best in the classroom – what did not work so well?
- Perceived pupils' reactions
- Logistics of organising the parents' session
- Experience of running parents session – advantages/disadvantages

Interviews with School Principals/Heads of Year

- Experiences of dealing with unintended pregnancies in the school
- Facilitators and barriers to current RSE provision
- Experience of informing/including parents in RSE
- Experiences of facilitating the intervention

Focus group Interviews with pupils

- The nature, quantity and quality of RSE currently taught in school
- Impressions of participating in the intervention
- Good and bad aspects of the intervention
- Is the intervention meaningful for girls as well as boys?
- Thought on including parents and a parent-child homework piece in the intervention
- Thoughts on what might be included in a webinar for teacher training

Focus group Interviews with parents

- Impressions of participating in the intervention
- Good and bad aspects of the intervention
- Is the intervention meaningful for girls as well as boys?
- Thought on including parents and a parent-child homework piece in the intervention
- Thoughts on what might be included on project website for parents
- Generally barriers and facilitators to implementing RSE in schools



8 Interview Topic Guides

Comparison Group

Increasing boys' and girls' intention to avoid teenage pregnancy: feasibility trial of an interactive video-drama based intervention in post-primary schools in Northern Ireland

Interviews with Teachers (at follow-up time point only)

- The nature, quantity and quality of RSE currently taught in school
- The specific nature of RSE taught in schools during the intervention period
- The specific nature of RSE relating to teenage pregnancy taught in the school during the intervention period or prior year.
- Experiences of recruiting pupils to conduct cognitive interviews
- Experience of liaising with parents
- Experiences of being in the control group

Interviews with School Principals/Heads of Year (at follow-up time point only)

- Experiences of dealing with unintended pregnancies in the school
- Facilitators and barriers to current RSE provision
- Experience of informing/including parents in RSE
- Experiences of being in the control group

Focus group cognitive Interviews with pupils on the questionnaire items

- Overall impression of completing the questionnaires
- What was hard/easy to understand?
- What pupils thought was being asked in each of the battery of questions.

9. RESOURCE USE QUESTIONNAIRE



Jack Trial

School Administrator Resource Use Record

This information will be used for reimbursement of postage expenses. It is also important for planning our future research as it will help us estimate staff and resources needed. Please provide as much detail as possible and indicate how long the activity took. If you forget to record this information at the time, you can estimate time taken but please indicate that it is an estimate on the form.

SCHOOL ID:

YOUR JOB TITLE:

Date	Activity (what <u>exactly</u> did you do?)	Who did the activity (role <u>not</u> name)?	Time taken (mins)
	Prepared and emailed Year 11 Class list		
	Prepared and printed Year 11 parent address labels		
	Attached address labels to envelopes		
	Prepared letters for posting to parents (franking machine or attached stamps?)		

	Cost of postage (per letter or total)		
	Anything else?		

Thank you very much for your help and for completing this form. Please return to Áine Aventin as soon as possible.

FIELD NOTE/OBSERVATION FORM

Your name	
Date & Time	
School ID	
Data Collection Activity	
Describe what happened	
Any interesting observations?	
Any problems?	

Other notes	

Appendix 3 Minutes of Steering Group meetings 1, 2 and 3



Jack Trial Steering Committee Meeting 1

9th October 2014 16:30 – 18:00

Newark Room, Lanyon, QUB

MINUTES

Apologies: Dr Darrin Barr¹; Ms Lisa Barr and Prof Hannah-Rose Douglas²

Present: Prof. Vivien Coates (Chair); Ms Grace McCarthy; Ms Chloe Templeton³; Dr Liam O'Hare; Mr. Patrick Lynn, Dr Maria Lohan; Dr Áine Aventin; Dr Suzanne Guerin (by telephone)

	ACTIONS
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AGENDA ITEMS

1. Role of steering committee

We began the meeting by talking through the role of the steering group committee. A welcome note with the roles of the group was also provided in writing to all of the members. The roles were outlined as follows:

- To provide advice, through its Chair, to the Chief Investigator, the Project Sponsor, the Project Funder on all appropriate aspects of the project
- To agree proposals for substantial protocol amendments
- To concentrate on progress of the project, adherence to the protocol & participant safety (The rights, safety and well-being of the participants are the most important considerations and should prevail over the interests of science and society)
- To ensure appropriate ethical and other approvals are obtained.

There was discussion about the extent to which the group was primarily a monitoring group or primarily an advisory group.

The Chair explained that it was mainly advisory – and would be mainly asked to advise on matters that the research team would bring to the meetings. For example, the group would not have to examine finances on the research project. However, all members were invited to ask questions of

the research team to ensure the study was conducted according to ethical standards for conducting research with schools, parents and pupils.

¹ Darrin was unable to attend but offered a follow-up phone call with the primary researcher Áine Aventin. As a school principal Darrin was able to advise on ways to succeed in recruiting schools and was hugely helpful.

² Hannah-Rose who is the Health Economics expert on the steering group was unable to attend. However Hannah-Rose sent a commentary to the research team on the health economics component of the trial, which we include here as Appendix 3.

³ Chloe also previously provided comments on the electronic version of the questionnaire in response to an e-mail communication with her.

2. Introductions

Maria informally introduced all members of the group. The objective of this introduction was to outline that each member brings a different type of expertise e.g. educational expertise, methodological expertise, experience of being a pupil in a similar school to those in the trial.

In short, the following points were noted:

- Vivien Coates as Chair is experienced Randomised Controlled Trial (RCT) Researcher and an expert in health research
- Grace McCarthy co-ordinates the Personal Development (PD which includes relationship and sexuality education (RSE)) programme at a post-primary school and is a member of the Board of Governors of another school
- Chloe Templeton is 16 years old and a 6th form pupil at Victoria College (single sex grammar school in Belfast)
- Liam O'Hare is a Senior Research Fellow at the Centre for Effective Education at QUB and a methodological expert in RCTs in educational settings
- Patrick Lynn is a 5th Form pupil at Methody College (co- educational, grammar school in Belfast)
- Suzanne Guerin is an experienced Chair of steering committees overseeing RCTs and is also an experienced RCT researcher
- Lisa Barr is a parent of teenage children.

- Darrin Barr is a Principal of a large second level girls school in Belfast and parent
- Hannah-Rose Douglas is a Health economist based in London.

Maria explained that the success of the project, in part, depended on being able to access these types of expertise and thanked each member individually for taking time to become involved.

3. Overview of project & overall progression (Maria)

Maria presented an overview of the project and progress to date. The overview of the project addressed the following questions:

- What is the intervention? (educational resource)
- Who designed the resource and what was the participation of statutory stakeholders?
- What are its qualities and why are we evaluating it?
- What is the research design and what is the rationale behind this design?
- An overview of progress to date. See Copy of these Slides Appendix 1

Vivien sought to ensure that everyone around the table gained an understanding of the research project and encouraged all members of the steering group to ask as many questions as necessary in order to understand the research design. A good discussion of some of the pertinent research issues ensued.

Discussion

Grace raised the question of whether recruiting at a Relationship and Sexuality Education (RSE) day presented a particular bias in the study. This bias was acknowledged but it was explained that this did not especially bias the results, because schools would be randomised independently after recruitment (to the intervention or control (comparison) group). Also, the research design depended upon schools taking the resource on – so it was normal to try and recruit schools which showed an interest.

There was also a concern raised about differences in all schools across NI in terms of the delivery of RSE and, therefore, the difficulty of comparing like with like. The two pupils commented that they had received very little RSE in each of their schools. It was covered, for example in biology, and perhaps through thinking about careers.

Maria acknowledged this variation also. She explained that part of the remit of this study was to collect information on what was normally delivered in each of the seven schools (largely through qualitative research methods) and this would help explain any variation in implementation and then also possibly the tentative results on impact of the resource. This component of the research would also tell us what types of schools we recruited based on their current delivery of RSE (referring back to previous question). Liam added that at this stage we are just capturing a picture of the variability that exists. In a larger effectiveness trial the numbers in both arms of the study

would be based on balancing out some of that variability across the two comparison groups (control and intervention).

Grace raised the concern that this intervention was a very major project for us and asked - What happens if it is not effective? Maria explained that we were happy to have the opportunity to study the intervention further in this study.

Vivien explained that the success of this study was not necessarily about the effectiveness of the intervention but more in terms of what we learn from this feasibility trial about how best to recruit schools and how best to deliver the intervention in classrooms. The effectiveness of the intervention would be studied in a larger trial – but depended first of all on the team's success in recruiting and implementing the intervention in this study in seven schools. Everything we learn in this first study (feasibility trial) will be very valuable in informing the optimal delivery of RSE in schools and also how researchers might introduce and evaluate this and other interventions. The Steering Committee members are vital to helping the research team access and better understand schools. In other words, the study will not be a failure as long as the researchers conduct this study in the way they said they would (on time and within budget). The results of the study are not as important as what we learn from the process.

4. Discussion items:

Recruitment of schools (Áine)

Áine presented an overview of the recruitment of schools to date. This was provided in writing and is attached as Appendix 2.

The main points covered were:

- Recruitment of schools in NI is designed to capture key differences in schools in NI in terms of management type (religion) and socio- economic profile of pupils attending (area based and level of free school meals).
- Recruitment strategy so far was through an RSE training day.
- Recruitment so far had progressed well but we were beginning to have concerns that we would find it difficult to recruit two 'Catholic grammar schools' and advice was sought on this point especially.

Discussion

Members of the steering group made very helpful suggestions as to how we might approach more schools and in particular Catholic grammar Schools.

Among the suggestions were:

- Check school websites for those with published RSE policy (e.g. Assumption Ballynahinch), as an indication of those who are interested in delivering RSE
- Try RC schools further south (out of cities e.g. Newry/Armagh – other border counties of Northern Ireland)
- Develop a flyer about the resource to go with the letter of invitation
- Contact (selectively) members of RC management of Schools
- Contact VP for pastoral care/PD co-ordinator in first instance.
- Dominican Portstewart as a possible contact.
- Telephone contact with schools is time consuming but good for recruitment of schools into research.

It was also acknowledged, especially by Suzanne and Liam, that this was still early days of recruitment and that there was no real sign of failure with any of the types of schools as yet.

Everyone was keen to be kept posted and to offer further advice as the need arose which was hugely appreciated by Áine and Maria on behalf of the research team.

Next meeting

A doodle poll of a small number of dates will be sent by email shortly to all members to arrange a next meeting for April 2015.

ACTIONS

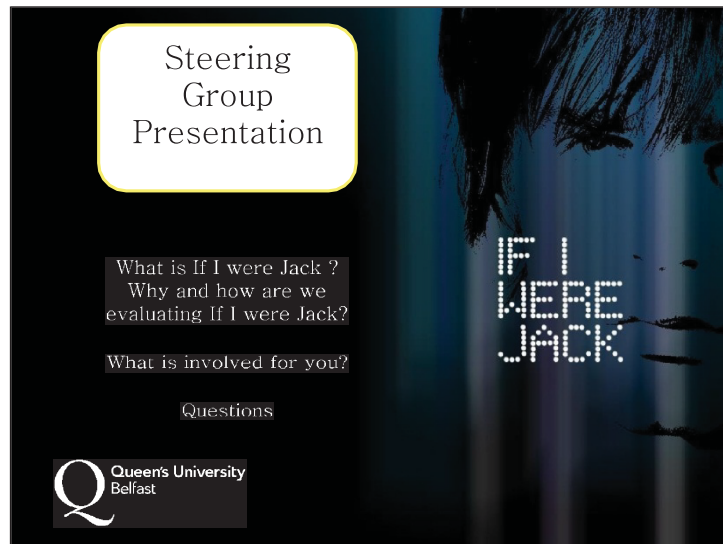
Maria to provide a copy of the study questionnaire to members of the steering group.

Áine to send list of RC schools in NI to Grace for further comment.

Maria to contact Laura Lundy re contacts at high level RC management advice.

APPENDIX 1: Presentation Slides

Slide 1




Slide

2



Slide 3

Who produced this educational resource?



3

Slide 4

Is it any good?

- Evidenced based
- Appropriate
- Engaging and Informative



Slide 5

But...it needs to be tested in a trial,


so that we can test whether these new methods are good for teachers and effective for pupils

Slide 6

How are we evaluating Jack ? Study Design

A Randomised Controlled Trial has 2 stages:

- Stage 1 tests how well a resource works in the classroom
- Stage 2 tests for effectiveness in educational outcomes



At stage 1 we need 7 schools

- 4 Intervention schools
- 3 Comparison Schools

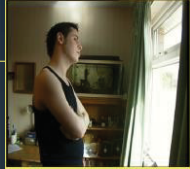

Slide 7

Study Design

To start: We gained ethical approval
& went to an RSE Training Day to inform teachers

Intervention schools:

- Deliver If I Were Jack during 4 RSE lessons
- Over a one year period Year 11 pupils complete a survey 3 times (during an RSE lesson) + an interview with teacher & some pupils






Slide 8

Study Design

Control Schools:

- RSE business as usual
- Over a one year period Year 11 pupils complete a survey 3 times (during an RSE lesson) + an interview with RSE teacher and some pupils





Slide 9

Study Design

Aim: Compare results of control and intervention arm

- 1) Use results to calculate a sample size for large trial
- 2) Assess acceptability and optimal conditions for delivery




9

Slide 10

What are the benefits of getting involved?

- Evidenced based education
- Supported by QUB with all the necessary information sheets for parents, pupils and ethical approval etc.
- Pupils will love it and teachers have said they really like it

Podcasts




It's better as experience than as a book could match

10

Slide 11

What do Schools do if they are interested?

- Give Research fellow contact details
- If school fits criteria we will send you more information and arrange to come and see RSE teacher & school principal)




IF I WERE JACK

Slide 12

What is the role of the steering Group?

- To provide advice, through its Chair, to the Chief Investigator, the Project Sponsor, the Project Funder on all appropriate aspects of the project
- To agree proposals for substantial protocol amendments




IF I WERE JACK

Slide 13

What is the role of the steering Group?

- To concentrate on progress of the project, adherence to the protocol & participant safety
- The rights, safety and well-being of the participants are the most important considerations and should prevail over the interests of science and society
- To ensure appropriate ethical and other approvals are obtained.




IF I WERE JACK

Slide 14

What is expected?

- Meet 4 times over study (May 2014- May 2016) (Next meeting May 2015)
- Research team will bring issues of concern to you (project operation or ethical issues)
- We will take a record of meeting and provide to you and NIHR (through Chair)



IF I WERE JACK

Slide 15

Acknowledgement of Research Funders



E·S·R·C
ECONOMIC
& SOCIAL
RESEARCH
COUNCIL



Department of
Health, Social Services
and Public Safety



HSC Public Health
Agency



crisispregnancyprogramme



NHS
National Institute for
Health Research



www.qub.ac.uk/IfIWereJack

Appendix 2

Overview of Recruitment

Jack Feasibility
Trial
Steering Committee
Meeting

Setting

Northern Ireland (NI) has a unique post-primary school system. Schools are categorised as 'secondary' and 'grammar' with the latter using academic ability to select pupils. Various *management structures* exist with 'controlled' schools managed by one of the five NI Education and Library Boards and 'voluntary' schools managed by a board of trustees (usually local churches). The Catholic Church manages a significant number of voluntary ('maintained') schools. Although religion is not a criterion for attendance at NI schools, most pupils at controlled schools are from Protestant denominations and most of those attending maintained schools are Catholic. There are also a number of 'integrated' schools, which aim to provide a religiously mixed environment.

TOTAL registered post-primary schools in NI 2013/14	210
Schools excluded:	9
1 was Irish language medium (secondary other maintained)	
8 < 30 Year 11 pupils in 2013/14 (5 secondary controlled; 3 RC maintained)	
Schools meeting inclusion criteria:	201
<i>Secondary</i> (133)	
Controlled (48)	
Controlled Integrated (5)	
Grant maintained Integrated (15)	
Roman Catholic maintained (65)	
<i>Grammar</i> (68)	
Controlled (17)	
Voluntary – Roman Catholic Managed (29)	
Voluntary – Other Managed (22)	
Schools approached (May- June '14):	8
Controlled Integrated (1)	
Controlled Grammar (1)	
Voluntary RC Managed (2)	
Voluntary 'other management' (2)	
RC Maintained Secondary (deprived area) (1)	
Schools recruited (May- June '14):	4

Controlled Integrated (1) Controlled Grammar (1) RC Maintained Secondary (deprived area) (1) Grant Maintained Integrated (deprived area) (1) <u>Voluntary RC Managed (0)</u> <u>Voluntary 'other management' (0)</u>	
Schools still to be recruited (Sept '14):	2
2 Voluntary RC Managed 1 Voluntary 'other management'	

Recruitment Target: 7 post-primary schools

In order to capture diversity, and reflecting the organisation of education in the unusual circumstances of NI, we aimed to recruit the following schools:

- 1 Controlled Integrated
- 1 Controlled Grammar
- 1 Voluntary 'Other' management
- 2 Voluntary Catholic Grammar
- 2 Secondary (any management type) in deprived areas

One of the aims of the feasibility study was to examine the acceptability of the intervention in different school types. Our preliminary research suggested that there may be challenges with implementation of a pregnancy related intervention in Catholic schools due to the fact that some may perceive the intervention not to be in line with the Catholic ethos. Conversely, we anticipated that there may be higher uptake of the intervention in deprived areas where teenage birth rates are higher. For this reason we aimed to recruit two of each kind of school and randomly assign one of each to the control group and the other to the intervention

group. Identification of Schools:

Strategy 1: RSE Training day (11 schools in attendance; 6 eligible for first round; 4/6 recruited) Recruitment as of end June 2014

- 1 Controlled Integrated ✓
- 1 Controlled Grammar ✓
- 1 Voluntary 'Other' management X
- 2 Voluntary Catholic Grammar X
- 2 Secondary (any management type) in deprived areas ✓

Reasons for non-participation

- 1 Catholic Grammar – Already involved in a research project
- 1 Catholic Grammar – Issues with intervention
- 1 Voluntary 'Other' management – Staff changes
- 1 Voluntary 'Other' management – Already involved in a research project

Schools still to be recruited (Sept/Oct '14)

1 Voluntary 'Other' management

2 Voluntary Catholic Grammar

Identification of schools (potential strategies)

Strategy 1: RSE training day, Strategy 2: Personal contact, Strategy 3: Principal/VP event,
Strategy 4: Invitation to all schools, Strategy 5: Ideas welcomed

Appendix 3

Comments from Hannah-Rose Douglas re Health economics questionnaire

If I were Jack: Comments on the economic protocol and questionnaire - Hannah-Rose Douglas

Economic evaluation section part of the protocol

1. My first comment is on the approach to collecting data on intervention costs. I assume the main cost driver will be teachers' time. I also assume that this intervention will be taking place during school hours and replace other RSE interventions that would otherwise have taken place. If so, the staff time to be included in the evaluation will be any additional time spent delivering this intervention over and above usual RSE lessons. I am sure you are aware of this, but wanted to make sure you were taking this marginal approach (looking at the additional costs and benefits of the intervention compared with usual practice rather than compared with no RSE intervention). I have seen this happen too often to presume it if it isn't explicitly stated so apologies if I am stating the obvious! If usual practice is to offer no RSE intervention, then the intervention should be compared with the activity that would otherwise have taken place during school hours. (If this were an out-of- hours activity, then the cost is the loss of teachers' leisure time but I don't think this is the case here). If the intervention replaces, say, a biology class, then the benefit of an RSE class using If I were Jack teaching tools would have to be compared with the loss of a biology lesson.

2. As you are aware, there are specific difficulties in economic evaluation when looking at interventions that affect fertility. If I put myself in the shoes of a decision-maker, I might ask myself, what is an acceptable cost to the public purse for an avoided teenage pregnancy? IN health care, there are now clear decision rules about the acceptable cost threshold for a quality-adjusted life

year (an additional £20,000 per additional QALY is sufficient for an intervention to be recommended by NICE for example). Teenage STIs avoided could be translated into QALYs, but this calculus does not take into account the additional (and more substantial) welfare gain for teenagers and society in postponing pregnancy. There are no easy answers to how to capture this welfare gain in economic evaluation, but I raise it now at the beginning of the

research process because ultimately decision- makers will have to address this issue when considering whether to spend scarce resources on this or similar interventions.

3. My final point is more of a plea. I have read many reports on the effectiveness of contraception and other interventions that reduce pregnancy that conclude that “for every £X spent, the health system will save £Y in unwanted pregnancy.” This way of reporting is beloved of decision-makers

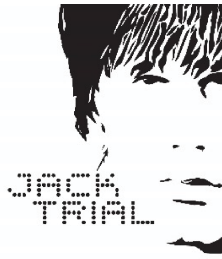
but is a complete fallacy. If this were the case, then the entire taxation budget should be invested in

pregnancy prevention and we would all be millionaires. Economic evaluation considers cost- effectiveness at the margin. At the start of any new public health education programme there are likely to be relatively more gains than at a later stage when extended to cover a larger population because those people who are more likely to change behaviour are likely to do so at relatively less cost. The wider the programme, the more of the population that is less likely to change their behaviour will be covered, reducing the relative effectiveness of the programme overall. In short,

costs and benefits change with expansion and over time. The cost-benefit ratio will also change. Therefore, any concluding statement that claims there will always be savings to the public purse from expansion of a specific programme is false. At some point, the benefit of expansion will be less than the benefit of expansion of another programme for the same cost. So I would be delighted if the research team could avoid the temptation of thinking about teenage pregnancy prevention in these simplistic terms (as I sure they never would anyway!)

Resource use questionnaire

1. This looks thorough. My overall reflection relates to point 1 above. At this stage, and without further background knowledge I assume that the time and resources required to deliver the If I were Jack intervention should be compared with usual RSE class preparation. If the intervention is planned to take place outside usual classroom teaching then it is not displacing any other activity (accept the teachers' leisure) that is fine, but if not, I think that you need to develop another (very similar) questionnaire to collect data on usual RSE lesson preparation to compare this intervention with.
2. You are not including the time cost to parents/carers of participating in feedback about the intervention which is fine but this could be stated in the protocol for clarity.
3. The time sheets only record time spent by the teacher alone preparing for and presenting the RSE class. There may also be some discussion between teachers in staff meetings, with the school senior management team and/or with the research team. This may be a substantial amount of time during the start-up phase and it may be helpful to have a prompting question about time spent in discussion with others on the form.



Jack Trial Steering Committee Meeting 2

11th May 2015 16:30 – 18:00

Newark Room, Lanyon, QUB

MINUTES

Present: Professor Vivien Coates (Chair); Dr Áine Aventin; Dr Darrin Barr; Ms Lisa Barr; Professor Hannah-Rose Douglas; Dr Suzanne Guerin; Dr Maria Lohan; Ms Grace McCarthy; Dr Liam O'Hare; and Ms Chloe Templeton.

Apologies: Mr. Patrick Lynn

AGENDA ITEMS	ACTIONS
<p>1. Introductions</p> <p>Led by the Chair, members introduced themselves and reminded colleagues of their role on the steering committee. In short, the following points were noted:</p> <ul style="list-style-type: none"> • Vivien Coates as Chair is experienced Randomised Controlled Trial (RCT) Researcher and an expert in health research • Áine Aventin is a post-doctoral research fellow at the School of Nursing & Midwifery and Trial Manager of the Jack Feasibility Trial • Hannah-Rose Douglas is a Health economist based in London • Chloe Templeton is a 6th form pupil at an all-girls grammar school in Belfast • Lisa Barr is a parent of teenage children • Darrin Barr is a parent and Principal of a large second level girls school in Belfast • Grace McCarthy a parent of teenage boys and co-ordinates the relationship and sexuality education (RSE) programme at a post-primary school and is a member of the Board of Governors of another school • Liam O'Hare is a Senior Research Fellow at the Centre for 	

<p>Effective Education at QUB and a methodological expert in RCTs in educational settings</p> <ul style="list-style-type: none"> • Suzanne Guerin is an experienced Chair of steering committees overseeing RCTs and is also an experienced RCT researcher • Maria Lohan is a senior lecturer at the School of Nursing and Midwifery and Chief Investigator of the Jack Feasibility Trial 	
<p>2. Progress Update (Maria)</p> <p>Maria provided the group with a brief reminder of the role of the steering committee members and continued with an overview of progress since the last meeting in September 2016.</p> <p>Key points were:</p> <ul style="list-style-type: none"> - The project is now half way through its two year duration. - We have met all project milestones to date. - At the last meeting recruitment was the biggest challenge. Maria informed the group that in the end we successfully recruited all schools with some minor adjustment to our stratification definitions so that we sought to recruit Catholic schools of any type rather than just Catholic Grammar schools. An overview of recruitment and summary tables were provided to the group (see Appendix 1). - Maria indicated that baseline data collection and implementation was complete in all schools and that we are currently planning the first follow-up data collection for June. - Aine has also completed all qualitative data collection in intervention schools. - Maria noted that one of the intervention schools almost withdrew from the study because the teacher who was to lead implementation had to go on long term sick leave. We were able to negotiate with the school so that one of their seven class groups used the intervention. - Maria thanked the steering group again for the help they provided in overcoming the challenges of recruitment and emphasised that this was 	

very valuable support.	
<p>4. Discussion items:</p> <p>Engaging Parents in School-based Activities (Áine)</p> <p>Áine presented an overview of a core challenge that we have experienced in engaging parents in the parental components of the intervention (parents' information and discussion session and parent/pupil homework exercise) (see Appendix 2 for overview)</p> <p>Discussion</p> <ul style="list-style-type: none"> - Liam raised the issue that if uptake of the parental components were extremely low or not being properly implemented that there was always the possibility that they could cause harm (i.e. have a negative impact on parent-child communication). - Suzanne shared that in her experience running parent sessions at different times of the day was more successful. She also thought that 'marketing' the event with a flyer rather than a letter might be more successful. Additionally she wondered of the requirement to send back a slip had put parents who never sent it back off attending. - Grace and Darrin agreed that it would be best placed tagged onto another event such as Year 11 parents evening or the welcome assembly style event for parents held at some schools at the start of the year. - Darrin recalled that his wife had attended a Love for Life parents' session at their child's school and it had been very well attended. He thought that it had taken place at 7pm. - Members agreed that the Video was a good idea and agreed that providing parents with information via video (and the option to engage in conversation with their child) rather than suggesting directly that they engage with the intervention directly might be more beneficial. - Members agreed that animations and short videos worked best. 	<p>Darrin to report back time and possible incentives for parents attending Love for Life parents' session</p>

<p>Suzanne suggested that a feedback video at the end of the study might also be good for parents.</p> <ul style="list-style-type: none"> - Suzanne suggested that having an external person deliver the parents session might be more beneficial as the parents might not like the idea of their child's teacher speaking to them about RSE. 	
<p>AOB</p> <p>Hannah-Rose, Lisa, Darrin and Grace said they would like to see the IVD.</p> <p>Hannah-Rose said that it would be useful to have a discussion about 'definitions of success' (i.e. outcomes) for a future trial</p> <p>Suzanne asked if the group could have an update on retention before the next meeting.</p> <p>Suzanne suggested that a possible means of conducting the parents' survey would be via text message. Darrin and Grace agreed, however, that it was not possible to reply to the school text messaging system.</p>	<p>Áine to send link to If I Were Jack IVD to members and asked them not to circulate it any wider than of themselves.</p> <p>Maria to add discussion of outcomes to agenda of October meeting</p> <p>Áine to forward retention figures to group ASAP following first follow-up.</p>
<p>Next meeting</p> <p>A doodle poll of a small number of dates will be sent by email shortly to all</p>	<p>Áine to send Doodle poll to members</p>

members to arrange a next meeting for October 2015.	
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APPENDIX 2: Discussion Item – Engaging Parents

JACK FEASIBILITY TRIAL

STEERING COMMITTEE MEETING

11th May 2015

Engaging Parents in Schools-based Activities

Background

- *A one-hour long parents' and guardians' information and discussion session is a core component of the If I Were Jack intervention.*
- *We sought to recruit at least one parent or guardian of each participating Year 11 pupil in the intervention group to attend a session at their child's school.*
- *Parents of pupils in the comparison group were not recruited to the study.*
- *Based on anecdotal evidence from teachers regarding difficulties engaging parents in non-academic activities, we estimated that parent/guardian representatives of approximately 50% of Year 11 pupils would attend these sessions, which should have resulted in around 200 participating parents from 4 schools.*

Results

- Three of the four intervention schools held the session. Late implementation start and teacher sick leave reasons for lack of session in one school.
- Recruitment of parents and guardians to attend the sessions was extremely low with an overall recruitment rate of 14.5% (n=10/292).
- Three schools held session in early evening (3.30/3.45/4.30 start)
- *In response to poor attendance at these sessions we recorded a six-minute information video which contained the key points from information session. This was posted on a locked YouTube channel and parents were sent a link to access it via email or text message.*
- 45 parents viewed the information session video on the YouTube channel.

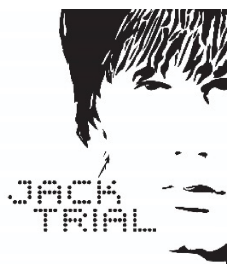
Reasons for non-participation

- Parents' survey planned

- Parents difficult to engage in general
- Subject matter – embarrassing; hypocritical; judgmental
- Practicalities - time of session; distance from school; child care arrangements
- Video – hyperlink not accessible; too long; text message not sent

Future Possibilities

- Incentives for travel, child minding etc.
- Increasing perceptions of benefits: video for parents that explained the significance of helping teenagers avoid teenage pregnancy and the impact that an unintended pregnancy might have on their lives
- Highlight non-judgmental nature of the intervention session
- Shorter video
- Child accompanies parent to session
- Other ideas?



Jack Trial Steering Committee Meeting 3
24th November 2015 16:00 – 18:00
School of Nursing and Midwifery, QUB
MINUTES

Present: Professor Vivien Coates (Chair); Dr Áine Aventin; Dr Darrin Barr; Dr Maria Lohan; Ms Grace McCarthy; Dr Liam O'Hare; Ms Chloe Templeton and Mr. Patrick Lynn

Apologies: Ms Lisa Barr; Dr Suzanne Guerin, Professor Hannah-Rose Douglas

AGENDA ITEMS	ACTIONS
<p>1. Chair's Welcome</p>	
<p>2. Progress Update (Maria)</p> <p>Key points were:</p> <ul style="list-style-type: none"> - The project is nearing completion with all data collection completed and analysis, write-up and dissemination are underway - We presented a report to NIHR on October 20th which reported that we had successfully met all progression rules to a Phase III effectiveness trial. - We expect to submit this application by December 18th 2015. - We have also obtained funding for the HSC R& D office to allow us to alter the parental component of the intervention for a face to face session to online engaging videos. - Maria thanked the steering group again for the help they provided thus far in advising on how we might overcome the 	

barriers to engaging with parents.	
<p>3. Next Meeting</p> <p>It was decided that a further meeting was not necessary since the trial was now essentially in a write-up phase</p>	<p>Maria to send out results summary on completion of report in May 2016</p>
<p>4. Appreciation</p> <p>The Chair and Chief Investigator sincerely thanked all of the members of the Steering Group for their contribution to the study.</p> <p>The members said they had enjoyed contributing to the study and wished Áine all the best with the forthcoming birth of her baby.</p>	

Appendix 4 The intervention

If I Were Jack key components, content and educational objectives

TABLE 47 *If I Were Jack* key components, content and educational objectives

When	Component	Content	Educational Objectives
Pre intervention	Teacher training session (60 minutes, online video and discussion forum)	<ul style="list-style-type: none"> Overview of the resource and its aims and objectives Demonstration of the IVD Overview of the classroom materials Overview of the parent discussion session Tips on successful delivery Sources of further information 	<p>By the end of the session teachers should:</p> <ul style="list-style-type: none"> have a clear understanding of the content and components of the intervention understand its key messages and educational objectives feel confident in being able to deliver the intervention understand the importance of fidelity to implementation protocol have had an opportunity to ask questions know where to access the resource and sources of further information
Pre intervention	Parent information and discussion session (60 minutes, teacher led)	<ul style="list-style-type: none"> Overview of the session Introduction ice-breaker Overview of the resource and its key messages Watch the <i>If I Were Jack</i> IVD Discussion: (1) views on the IVD; (2) How would you respond if Jack was your son or Emma your daughter? (3) Do we send different messages to our sons and daughters about pregnancy? (4) What can we do to prevent teenage pregnancy? (5) Talking about relationships and sexuality with our teenagers: challenges and tips Wrap-up Parents provided with <i>If I Were Jack</i> parents' factsheet which contains an overview of the resource, facts and myths about teenage pregnancy, tips for speaking to teenagers about relationships and sexuality and sources of further information 	<p>By the end of the session parents should:</p> <ul style="list-style-type: none"> have a clear understanding of the content and components of the intervention understand its key messages feel confident in being able to complete the parent/guardian survey with their teenager have had an opportunity to ask questions know where to access the resource and sources of further information
Week 1	<i>If I Were Jack</i> overview and ground rules	<ul style="list-style-type: none"> Teacher provides overview of the resource and its key messages Sets ground rules emphasising the need for respect, involvement, confidentiality and equality 	<p>By the end of the lesson pupils should be able to:</p> <ul style="list-style-type: none"> recognise that UTP can be a stressful experience and can have some negative consequences

continued

TABLE 47 *If I Were Jack* key components, content and educational objectives (continued)

When	Component	Content	Educational Objectives
	<i>If I Were Jack</i> IVD	<ul style="list-style-type: none"> Pupils spend 25 minutes on individual computers with headphones. Watch film depicting a week in the life of 16-year-old Jack, who has just found out that his girlfriend is unexpectedly pregnant and respond to on-screen questions when prompted. Questions ask the user to consider what they would do/think/feel if they were Jack If individual computers not available, teacher shows the film on overhead screen and pupils complete paper questionnaires containing questions embedded in the IVD 	<ul style="list-style-type: none"> begin to understand the roles and responsibilities of young men in relation to unintended pregnancy recognise the impact that having a baby would have on their daily life
	Homework: 'If I had a baby' activity and <i>If I Were Jack</i> factsheet	<ul style="list-style-type: none"> The 'If I had a baby' activity asks the pupil to complete a worksheet which compares the schedule of a 6-month-old baby and parent to their own current schedule and to consider the impact that having a baby might have on their current life and future goals Factsheet contains an overview of the resource, facts and myths about teenage pregnancy, and sources of further information about relationships, sexuality and unintended pregnancy 	
Week 2	Group discussion: 'If I had a baby' activity and <i>If I Were Jack</i> factsheet	<ul style="list-style-type: none"> Group discussion about the homework activities with particular focus on the potentially negative consequences that an unplanned pregnancy might have on their current life and future goals 	By the end of the lesson pupils should be able to: <ul style="list-style-type: none"> recognise that UTP is a stressful experience and can involve some very difficult decisions identify potential consequences of UTP
	Group discussion: Pause: Fast Forward: Rewind activity	<ul style="list-style-type: none"> Pupils think about and discuss Jack and Emma's story and the implications that the pregnancy might have for their current situation and future and how they might have avoided an unplanned pregnancy 	<ul style="list-style-type: none"> identify the means of preventing unintended pregnancy demonstrate their knowledge of local counselling services and sources of online information related to unintended pregnancy and sexual health
	Homework: online scavenger hunt activity	<ul style="list-style-type: none"> The 'online scavenger hunt' worksheet contains a list of four websites and four questions. Pupils must access the websites (which relate to sources of information about relationships and sexuality and unintended pregnancy support services) in order to find the answers to the questions 	

TABLE 47 *If I Were Jack* key components, content and educational objectives (continued)

When	Component	Content	Educational Objectives
Week 3	Group discussion: online scavenger hunt	<ul style="list-style-type: none"> A fifth question requires pupils to find a website with information that might be useful for teenage boys Group discussion based around the answers to the questions in the homework task Discuss whether or not they think there is sufficient information available for young men 	By the end of the lesson pupils should be able to:
	Small group work and discussion: 'Making a difficult decision'	<ul style="list-style-type: none"> Brainstorm the consequences of the different pregnancy resolution options referred to in the video and discuss how this would be a difficult decision affected by individual values Work in small groups and use the 'Making a difficult decision' worksheet to think about the short- and long-term advantages and disadvantages of each of the options 	<ul style="list-style-type: none"> identify the potential consequences of UTP demonstrate that they could offer advice and accurate information to someone who was experiencing an unintended pregnancy demonstrate effective communication about unintended pregnancy
	Small group work and discussion: 'Dilemmas'	<ul style="list-style-type: none"> Practice giving advice on 'real-life' dilemmas (four fictional e-mails) using the knowledge that they have gained about unintended pregnancy 	
	Homework: parent/guardian survey	<ul style="list-style-type: none"> Pupils ask one or both of their parents or guardians (or another trusted adult) to watch <i>If I Were Jack</i> (or read an excerpt of the script) and then ask them the questions on the parent/guardian survey worksheet 	
Week 4	Group discussion: parent/guardian survey	<ul style="list-style-type: none"> Discussion about pupils' experiences of doing the parent/guardian survey 	By the end of the lesson pupils should be able to:
	Group discussion: controversial statements	<ul style="list-style-type: none"> A discussion activity that encourages pupils to consider stereotypical norms relating to gender and social class and how they relate to sexuality and pregnancy 	<ul style="list-style-type: none"> discuss the roles and responsibilities of young men and young women in relation to unintended pregnancy and how these are affected by gender stereotypes
	Role-play activity	<ul style="list-style-type: none"> Work in small groups to write and perform one of four role plays depicting conversations relating to relationships and pregnancy Whole group feedback to performers regarding what they did well and/or could have done better 	<ul style="list-style-type: none"> demonstrate effective communication about unintended pregnancy recognise the importance of deciding on a plan to ensure that they avoid unintended pregnancy

continued

TABLE 47 *If I Were Jack* key components, content and educational objectives (*continued*)

When	Component	Content	Educational Objectives
	Wrap-up: complete my plan activity	<ul style="list-style-type: none"> Individual worksheets which encourage pupils to think about how they would feel if they or their partner was pregnant now; the circumstances under which they would like to have a baby in the future (e.g. when finished studying, married, etc.); and to formulate a plan for avoiding an unintended pregnancy 	

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Components and targeted psychosocial variables of the intervention

TABLE 48 Outcomes and outcome measures

Targeted psychosocial variables		Related components of the intervention
Knowledge	Knowledge of ways of avoiding unintended pregnancy	<i>If I Were Jack</i> factsheet Pause: Fast Forward: Rewind activity
	Knowledge about sources of support for unintended pregnancy	<i>If I Were Jack</i> factsheet Online scavenger hunt Parent/guardian survey
	Knowledge about the possible negative relational, social, emotional and financial consequences of unintended pregnancy	Modelling of consequences in the IVD <i>If I Were Jack</i> factsheet 'Making a difficult decision' activity Pause: Fast Forward: Rewind activity 'If I had a baby' activity Parent/guardian survey
	Knowledge about the roles and responsibilities of teenage males in relation to unintended pregnancy	Modelling of male role in the IVD <i>If I Were Jack</i> factsheet All discussion activities
Skills	Communication skills to discuss unintended pregnancy with peers and parents	Modelling of verbal scripts in the IVD Role-play activity 'Dilemmas' activity 'Controversial statements' activity Parent/guardian survey
Sociocultural influences	New awareness of peer norms regarding sexual behaviour and unintended pregnancy	<i>If I Were Jack</i> factsheet All discussion activities

TABLE 48 Outcomes and outcome measures (*continued*)

Targeted psychosocial variables		Related components of the intervention
	New awareness of the impact of gender norms and stereotypical beliefs that avoiding and dealing with the consequences of an unintended pregnancy is a woman's responsibility	Modelling of gender norm activity in the IVD 'Controversial statements' discussion activity 'Dilemmas' activity
	New awareness of parental attitudes, values and beliefs in relation to unintended pregnancy and unintended pregnancy outcomes	Consideration of personal attitudes, values and beliefs while engaging with the IVD 'Making a difficult decision' activity 'Dilemmas' activity 'Controversial statements' activity 'My plan' activity
Beliefs about behavioural control	Improved self-efficacy in ability to communicate about unintended pregnancy with parents, peers and professionals	Modelling of communication strategies and verbal scripts in the IVD All discussion activities Role-play activity Parent/guardian survey
	Improved perceived behavioural control in avoiding unintended pregnancy	<i>If I Were Jack</i> Factsheet Pause: Fast Forward: Rewind activity Personal reflection while using the IVD and engaging in other activities
	Anticipated regret about the negative impact of unintended pregnancy on current life and future goals	Modelling of consequences in the IVD <i>If I Were Jack</i> Factsheet 'Making a difficult decision' activity Pause: Fast Forward: Rewind activity 'If I had a baby' activity Parent/guardian survey Personal reflection while using the IVD and engaging in other activities
Intention	Increased intention to avoid unintended pregnancy	Personal reflection while using the IVD and engaging in other activities 'My plan' activity

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Appendix 5 Outcomes and outcome measures

TABLE 49 Outcomes and outcome measures

Component	Aim	Measurement
Knowledge	Increase knowledge about ways of avoiding unintended pregnancy; roles and responsibilities of young men in relation to unintended pregnancy; possible negative relational, social, emotional and financial consequences of unintended pregnancy; and sources of information and support for unintended pregnancy	Individual assessment. Total score on 10 knowledge items. Selected items from the Mathtech Knowledge Inventory ¹⁶⁴ and SKATA ¹⁶⁵
Communication skills	Increase skills for communicating with parents and peers about avoiding unintended pregnancy	Comfort Communicating about Pregnancy scale (parents, peers and professionals). Selected items from the Mathtech Behaviour Inventory ¹⁶⁴
Attitudes about unintended pregnancy	Increase anticipated regret about the consequences of unintended pregnancy on current life and future goals	Items from the newly developed TUPS
Social influences	Increase awareness of peer norms, stereotypical gender norms and parental attitudes and beliefs about teenage pregnancy	Male role gender norms: Male Role Attitudes scale ¹⁶⁶ and knowledge items relating to responsibility for avoiding pregnancy
	Gender norms: increase perception that both men and women have roles and responsibilities in avoiding and dealing with the consequences of unintended pregnancy	Peer norms: knowledge items about sexual behaviour/contraceptive use among peers and Sexual Socialisation instrument (Peer subscale) ¹⁶⁷
	Peer norms: increase perception that most peers are not sexually active and use contraception when they are	Parental values and beliefs: Sexual Socialisation instrument (Parent subscale) ¹⁶⁷
	Parental values and beliefs: increase awareness of parental attitudes and beliefs about unintended pregnancy	
Beliefs about capabilities	Increase perceived behavioural control to avoid unintended pregnancy (say no to sex or obtain and use contraception correctly) and increase self-efficacy to communicate about avoiding unintended pregnancy with parents, peers and professionals	Sexual Self-Efficacy scale using an adapted version of the Sexual Self-Efficacy scale ¹⁶⁸
Intentions	Increase strength of intention to avoid UTP	TUPS (constructed by research team)
Sexual behaviour	Abstinence from sexual intercourse (delay initiation of sex or return to abstinence) or avoidance of unprotected sexual intercourse (consistent correct use of contraception)	Sexual behaviour items (ever had sexual intercourse; frequency of sexual intercourse; contraception use ever/at last intercourse). Items adapted from previous sexual health surveys ^{121,153}
Pregnancy	Avoidance of unintended pregnancy	Ever pregnant
SKATA, Sexual Knowledge and Attitude Test for Adolescents.		

Appendix 6 Relationship and Sexuality Education provision within the personal development strand of the Learning for Life and Work Northern Irish curriculum

This includes the 'Insync' PD programme developed by CCEA at Key Stage 3 (Years 8–10). Relationships and sexuality is one of 10 themes within the programme, which are as follows:

Theme 1 – Health and the Whole Person

Theme 2 – Feelings and Emotions

Theme 3 – Managing Influences and Making Decisions

Theme 4 – Self Concept

Theme 5 – Managing Change

Theme 6 – Morals, Values and Beliefs

Theme 7 – Learning About Learning

Theme 8 – Safety and Managing Risk

Theme 9 – Relationships and Sexuality

Theme 10 – Drugs Awareness.

For a programme overview for Year 8 see www.nicurriculum.org.uk/docs/key_stage_3/insync/yr8/teacher_notes/y8_overview.pdf, for Year 9 see www.nicurriculum.org.uk/docs/key_stage_3/insync/yr9/teacher_notes/y9_overview.pdf, and for Year 10 see www.nicurriculum.org.uk/docs/key_stage_3/insync/yr10/teacher_notes/y10_overview.pdf.

The statutory requirements for PD within the NI curriculum are accessible via http://ccea.org.uk/sites/default/files/docs/curriculum/area_of_learning/learning_life_work/pers_dev/ks3_personaldev.pdf.

The non-statutory guidance document for PD is accessible via http://ccea.org.uk/sites/default/files/docs/curriculum/area_of_learning/learning_life_work/pers_dev/ks3_pd_nonstat_guidance_Aug2011.pdf.

Updated guidance for RSE for post-primary schools, published in August 2015, is accessible via http://ccea.org.uk/sites/default/files/docs/curriculum/area_of_learning/pdmu/rse/RSE_Guidance_PostPrimary.pdf.

Appendix 7 Number of contacts, outcomes and time taken to decide by schools approached

TABLE 50 Number of contacts, outcomes and time taken to decide by schools approached

School type	Recruitment strategy	Number of contacts prior to decision	Time to decide after first contact	Outcome	Reason for outcome
May–June 2014					
Controlled integrated	Head of LLW attended April RSE training day	3	8 days	Agreed to participate	Intervention considered compatible with needs Keen to get involved with more research
Controlled grammar	Head of Year 11 attended April RSE training day	9	15 days	Agreed to participate	Credibility of the intervention/research PC VP expressed initial hesitation until a colleague talked positively about the study at a training event
RC grammar	Advisory group member introduced	6	19 days	Refusal	Intervention considered incompatible with school ethos
RC grammar	Cold-call approach	5	11 days	Refusal	Already involved in other research
Grant maintained integrated	RSE co-ordinator attended April RSE training day	2	1 day	Agreed to participate	Intervention considered compatible with needs
RC secondary	RSE co-ordinator attended April RSE training day	2	2 days	Agreed to participate	Intervention considered compatible with needs Involvement in research considered evidence for development of RSE programme at upcoming inspection
Voluntary other managed	RSE co-ordinator attended April RSE training day	5	9 days	Refusal	Inappropriate timing: LLW staff changes
Voluntary other managed	Cold-call approach	4	2 days	Refusal	Already involved in other research
September–October 2014					
RC grammar	Cold-call approach	4	5 days	Refusal	Reason for refusal not communicated
RC grammar	Cold-call approach	1	1 day	Refusal	Already involved in other research
RC grammar	Cold-call approach	5	6 days	Refusal	No space for intervention in the Year 11 LLW curriculum

continued

TABLE 50 Number of contacts, outcomes and time taken to decide by schools approached (*continued*)

School type	Recruitment strategy	Number of contacts prior to decision	Time to decide after first contact	Outcome	Reason for outcome
RC grammar	Cold-call approach	2	4 days	Refusal	Reason for refusal not communicated
RC grammar	Advisory group member introduced	1	1 day	Refusal	No space for intervention in the Year 11 LLW curriculum
RC grammar	Senior teacher attended October RSE training day	2	2 days	Agreed to participate	Credibility of the research Intervention considered compatible with needs (resources for teenage males)
Voluntary other managed	Steering group member introduced	5	No response after final contact (15 days post first contact)	Non-response	All telephone contact via Principal's PA. She said they usually had a 'no research' policy
Voluntary other managed	RSE co-ordinator attended October RSE training day	1	1 day	Refusal	Inappropriate timing: No space for intervention in LLW curriculum and conflict with exams
Voluntary other managed	Teacher attended October RSE training day	2	2 days	Refusal	Intervention considered incompatible with needs ('no problems with teenage pregnancy' and existing comprehensive RSE provided by external facilitators)
Voluntary other managed	Steering group member introduced	4	18 days	Agreed to participate	Credibility of the research
Controlled secondary	Head of LLW attended April RSE training event	1	1 day	Agreed to participate	Intervention considered compatible with needs (teenage pregnancy resources)
RC secondary	Advisory group member introduced	1	2 days	Refusal	Inappropriate timing: no space for intervention in LLW curriculum
RC secondary	Teacher attended April RSE training day	2	1 day	Agreed to participate	Intervention considered compatible with needs (teenage pregnancy resources) Positive experiences participating in past research

PA, personal assistant.

Appendix 8 School and pupil report



THANK YOU!

Feedback to pupils



The *JACK Trial* Team at Queen's University Belfast would like to thank all the pupils, teachers and parents who gave up their time to take part in the research. Without your help the study would not have been possible.

The work we did with you was so successful that JACK is now travelling to Scotland, Wales, England and all over Northern Ireland on a new study with thousands of pupils across the UK.



Thanks to you, we've made lots of changes to the *If I Were Jack* film and activities. We've also improved the questionnaires and the way we carry out the research.

Here are just some changes that we will make as a result of your feedback:

**YOU
SAID!**

- The film looks a little old-fashioned, especially Jack's phone, and it's cheesy at times.
- Most of us don't like homework activities.
- We don't want to do the questionnaire so many times.
- Some of the words and questions you use are difficult for us to understand.
- Don't plan research activities just before school holidays or exams.
- Make sure we have enough space so other pupils and teachers can't see what we are filling in the questionnaires.
- My parents couldn't come to the information sessions so they didn't know what was happening in class.

**WE
DID!**

- We're making a new version of the film with more modern phones and less cheese!
- We've removed all of the homework apart from the parents' survey.
- Pupils will now fill in the questionnaire twice instead of three times.
- We've changed the words and questions you told us to change!
- We will now ask teachers to do the Jack lessons in the middle of term time.
- In the new study we will ask teachers to stand at the front of the hall and make sure that there is plenty of space between the desks.
- We're replacing the parents information session with two animations which we'll send to them.

The new JACK research study is taking place right now and will end in 2020.

On a bigger scale, we will find out the benefits of the *If I Were Jack* resource for pupils across the UK. And it's all thanks to you!



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Health Research**



THANK YOU!

Feedback to schools



The JACK Trial Team at Queen's University Belfast would like to thank all the teachers, pupils and parents who gave up their time to take part in the research. Without your help the study would not have been possible. Now that we've finished this part of the study, we thought you might like to know what we found and what we plan to do next.

- The aim of the study was to test a Relationship and Sexuality Education (RSE) resource called *If I were Jack*.
- 831 Year 11 pupils, 48 teachers and 8 schools in Northern Ireland took part.
- Four schools were randomly chosen to use the If I were Jack resource during four weekly sessions.
- All Year 11 pupils in the participating schools completed a questionnaire three times between November 2014 and October 2015.
- We talked to pupils, teachers and parents to find out what changes we need to improve the resource and to make it more interesting and useful.

WHAT WE DID

RSE in Schools

As part of the study we also asked a sample of teachers and pupils for their thoughts on existing RSE provision in schools in Northern Ireland.

- In general, it emerged that RSE provision was extremely variable and not perceived as a priority subject in most participating schools. Some schools had clearly structured RSE programmes whereas others had difficulty articulating their RSE provision. Most pupils recalled little to no previous attention or emphasis placed on unintended teenage pregnancy.
- Teachers reported a general sense that RSE provision remained somewhat sensitive, controversial and that attitudes towards RSE were highly variable, with some reports of religious conservatism and homophobia, and that improvements could be made.
- Teachers reported that post-qualifying training and opportunities for training in RSE appeared to be all but absent.
- Teachers welcomed new resources such as this which take a fresh approach to RSE and are sensitive to the needs of schools.

YOU SAID!

WE DID!

You made great suggestions about ways that we could improve the resource, the questionnaires, and the way we carry out the research. Here are just some changes that we will make as a result of your suggestions:

- Make a new modern version of the film and reduce the number of questions contained within it.
- Remove most of the homework activities and update other activities based on your suggestions.
- Replace the parents/guardians' information session with two animated films which help parents have conversations with their teenagers about sex and relationships.
- Use paper copies of the questionnaire to avoid possible technical difficulties completing online.
- Pupils complete the questionnaire twice instead of three times.

WHAT NEXT?

You have made a very positive contribution to the future development and evaluation of *If I Were Jack*. As a result of your suggestions we have improved the resource and are now setting up a UK-wide study which will determine if the *If I Were Jack* resource can help young people avoid unintended teenage pregnancy.



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National Institute for Health Research

Appendix 9 Connections between qualitative and quantitative components in meeting key objectives

TABLE 51 Connections between qualitative and quantitative components in meeting key objectives

Objectives of the research	Qualitative component	Quantitative component
Assess the acceptability of the intervention to schools (principals and RSE teachers), pupils and parents	Single and focus group interviews will be conducted with these participants in intervention arm to assess how the intervention is received	Measured in terms of success of being implemented
Identify optimal delivery structures and systems for the delivery of the resource in the classroom	Single and focus group interviews will be conducted with teachers pupils and school principals	
Establish intervention participation rates and reach including equality of engagement across schools of different socioeconomic and religious types	Telephone interviews with schools that choose not to participate	Measured through sampling and recruitment procedures
Assess trial recruitment and retention rates	As above and obtaining information (where possible) for withdrawals ^a	Measured through sampling and recruitment procedures
Assess variation in normal RSE practice across the participating schools	Obtained through an interview with all relevant RSE teachers in intervention and control arms and an examination of any materials they might offer us	
Refine survey instruments as a result of cognitive interviews with male and female pupils	Cognitive interviews with a sample of pupils in control arm	
Assess differences in outcomes for male and female pupils	Interviews with pupils may aid explanation	Measured through quantitative instruments
Identify potential effect sizes that might be detected in an effectiveness trial and estimate appropriate sample size for that trial		Measured through quantitative outcome measures at baseline and follow-up
Identify the costs of delivering <i>If I Were Jack</i> and pilot methods for assessing cost-effectiveness in a future trial	Additional clarification will be sought in interviews with school principals and teachers	Measured using a template recommended by Ritzwoller <i>et al.</i> ¹³²
^a Schools have the right to withdraw without providing a reason under the ethics principles of the study.		

Appendix 10 Content, frequency and delivery of Relationship and Sexuality Education in participating schools

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Trial Allocation		Intervention schools				Control schools			
School ID		13	14	15	17	10	11	12	16
Year 10		4–6 lessons	4 lessons	8 lessons	4–6 lessons	4–5 lessons	3–4 lessons	4 lessons	
		LLW team	LLW team	PC	LLW team		Increasing self-esteem and informed decision-making		
		Relationships, pregnancy myths; contraception, STIs	Boyfriends and girlfriends; introduction to common STIs	Managing change – self awareness	Dating Relationships; Consequences of sex; STIs; pregnancy; abortion; parenthood		6 lessons		
		1 lesson 'Icebergs and Babies'		Feelings and emotions; – understanding feelings, thinking about behaviour, coping with feelings			'Teen Star' programme – the effect of the media on young people		
		'Love for Life'		Relationships and sexuality; – the implications of sexual maturity (e.g. conception, teenage pregnancy, underage parenting)					
		Implications of early sex; STIs; pregnancy as a consequence of early sex		LLW					
				6–8 lessons					
				Safety and managing risk					
continued									

TABLE 52 Content, frequency and delivery of RSE in participating schools (*continued*)

Trial Allocation		Intervention schools			Control schools			
School ID	13	14	15	17	10	11	12	16
Year 11	LLW not offered at Key Stage 4	4 lessons for pupils taking LLW GCSE	6–8 lessons	5 lessons	LLW not offered at Key Stage 4	3–4 lessons PC	4 lessons PD	
	1 session	Complete 'Sex and Relationships Education' booklet focus on qualities of good parents; relationships and relationship breakdown; contraception; STIs; myths of pregnancy	PC	LLW team; school nurse	1 lesson (girls only)	Increasing self-esteem and informed decision-making		
	Local Area Project: group work on safe choices, future aspirations; sexual health, assertiveness and communication	Relationships and Sexuality: (i) Dating – understanding the nature of relationships; (ii) Dating – sexual behaviour; sexuality and responsibility; STIs; teenage pregnancy and its consequences; myths of teenage pregnancy; homosexuality	Relationships and Sexuality: (i) Dating – understanding the nature of relationships; (ii) Dating – sexual behaviour; sexuality and responsibility; STIs; teenage pregnancy and its consequences; myths of teenage pregnancy; homosexuality	Pregnancy myths; contraception; STIs; sex and the law (Jack to replace above lessons for the one participating class group)	Family planning nurse from local health centre	Half-day 'Love for Life' session		
					6 lessons			
					'Preparing for Adult Life' Units on relationships; roles and responsibilities as parents			
			4–5 sessions					
			GCSE LLW					
			Concept of self, managing emotions and reactions					
			Recognising assessing and managing risk					
			Understanding relationships and sexuality and the responsibilities of healthy relationships					

Trial Allocation		Intervention schools			Control schools				
School ID		13	14	15	17	10	11	12	16
Year 12		6–10 lessons Parenting awareness module for pupils taking extra-curricular courses	3 lessons LLW STIs, contraception	GCSE LLW Development repeat students only Content as per Year 11	4–6 lessons LLW Definitions of 'Sex'; Consequences of Sex – positive/negative; STIs; AIDS; Negotiating Sex; Sex and the Law/Sexuality	Not reported	3–4 lessons PC Increasing self-esteem and informed decision-making		
Years 13/14		2 lessons Guest speakers from Action Cancer and the Rainbow Project (LGBT issues)	None	8 Lessons PC Relationships and Sexuality Sexuality and responsibility; explore a range of issues arising (e.g. social media, cyber bullying, CSE, alcohol and drugs use, sexual exploitation, independent living at university)	4 lessons LLW team STIs; Nexus – talk given by outside agency; relationships – casual vs. serious; gender differences in attitudes to sexual relationships	Not reported	Half day 'Love for Life' session in Year 13		Knowledge is Power Quiz
Received by current Year 11 group?		LLW/PD content and puberty talk only	Yes	Yes. Pregnancy activities at Year 11 replaced with Jack	Yes. Jack replaces those listed at Year 11 for one class group	Yes	Yes		
AIDS, acquired immunodeficiency syndrome; CSE, child sexual exploitation; LGBT, lesbian, gay, bisexual, transgender.									

Appendix 11 Suggested changes to the intervention (pupils and teachers combined)

TABLE 53 Suggested changes to the intervention (pupils and teachers combined)

Component	Description	Suggested changes
IVD	Film	<ul style="list-style-type: none"> Engage teenagers to revise script so that dialogue is less 'cheesy' Update aspects of film (e.g. mobile phone, fashion) Leave option of viewing on overhead screen or individual computers Consider ending
	Text within film. 27 questions with multiple-choice answer sets	<ul style="list-style-type: none"> Reduce the number of questions asked Remove repetitive questions/response sets (i.e. what would your mum say/what would your dad say?) Consider 'other' open-ended option Rewrite text messages in consultation with teenagers Option for teacher to show the film without the questions?
Jack factsheet	Homework. Doubled-sided A4 sheet to read. Contains information on intervention, a 'fact or fiction' quiz focused on teenage pregnancy myths and website addresses	<ul style="list-style-type: none"> Incorporate fact or fiction activity into lesson – perhaps use overhead to place questions and allow group discussion of answers Consider providing pupils with 'wallet cards' of important information/contacts/websites rather than a sheet
If I had a baby	Homework. Doubled-sided A4 worksheet. Pupils compare their schedule to that of a parent with a 6-month old baby and are asked to consider what they would miss most and how their current life and future goals might change if they had a baby	<ul style="list-style-type: none"> Incorporate activity into lesson Some thought that completion of the young person's schedule was unnecessary; others thought that it reinforced what would be missing Clarify if pupils should include school day or weekend/holiday schedule
Pause: Fast Forward: Rewind	Teacher-led discussion about what happened in the film, what might happen next and how the situation might have been prevented	<ul style="list-style-type: none"> Remove repetitive questions already contained in the film (e.g. how would you feel? what would you do?) Consider enhancing the focus on how the story ends Provide worksheet
Online scavenger hunt	Homework. Single A4 sheet. Pupils access four websites to find the answers to four questions	<ul style="list-style-type: none"> Incorporate teacher-led activity into lesson Ensure websites can be accessed on school internet network
Making a difficult decision	Single A4 worksheet. Small group work and whole class discussion of the pros and cons of pregnancy outcomes for Jack, Emma and baby	<ul style="list-style-type: none"> Remove repetition Consider removing or reworking 'pros' of abortion for baby (perhaps indicate that it is acceptable to state that there are no pros, consider changing wording from 'pros' and 'cons' to 'good things' and 'bad things')
Dilemmas	Small group work. Pupils read dilemma e-mail and write a response	<ul style="list-style-type: none"> Include option to complete task as discussion exercise Engage teenagers to revise dilemma e-mails/ensure that they are more realistic Consider how we might remove/make optional the written element Consider any repetition between dilemmas and other activities

continued

TABLE 53 Suggested changes to the intervention (pupils and teachers combined) (*continued*)

Component	Description	Suggested changes
Parent survey	Homework. Pupil asks parent(s)/ guardian(s) or other trusted adult to watch excerpt of film and answer three questions	<ul style="list-style-type: none"> • Make this an optional exercise • Permit pupils to complete survey with older brother/ sister or other trusted adult • Consider how might include peer element (e.g. survey a friend <i>and</i> an adult) • Consider providing typed extract for those with no internet access only
Controversial statements	Whole group discussion. Individual pupils pick out statement and give their opinion	<ul style="list-style-type: none"> • Consider revising this activity so that there is a more obvious 'fit' • Consider positioning at beginning as a tool for sparking discussion of pregnancy stereotypes/male roles and responsibilities • Consider keeping statements focused on pregnancy-related stereotypes only • Consider allowing small group discussion prior to expressing individual views or reformat to a large group discussion
Role play	Small groups of pupils write script, act out and discuss as a whole group	<ul style="list-style-type: none"> • Make an optional exercise or remove entirely • Correct missing text on scenario 3 card • Consider emphasising 'script-writing' rather than 'acting out' the scenario
My plan	Homework. Single A4 worksheet. Pupils answer four questions and consider how they will avoid UTP	<ul style="list-style-type: none"> • Consider revising to teacher-led/classroom-based activity • Consider how we might rework as a non-written exercise
Training	60-minute face-to-face training session	<ul style="list-style-type: none"> • Retain for full trial • 10- to 15-minute online video post trial • Consider option for one teacher to attend training and feedback to others?
Parents' session	60-minute information and discussion session for parents facilitated by teacher	<ul style="list-style-type: none"> • Consider ways of engaging parents that do not involve parents attending school • Consider use of film/animation sent to parents via text message with the aim of encouraging them to have a conversation with their child about teenage pregnancy

Appendix 12 Field worker reflections on data collection in schools

Themes

- (a) School environment: computer equipment, pupil proximity, teacher involvement, timing.
- (b) Pupil issues: confusion, confidentiality and legal issues, family circumstances.
- (c) Researcher issues: challenging behaviour, additional support.

(A) School environment

i. Computer equipment:

- online questionnaire was very problematic – even with computer staff there for support
- very frustrating for young people using it as they had to log on numerous times within a session and many lost answers that they had given
- some pupils could not log on because they forgot their log-in details for the school system. They were not aware that they could use other pupils' log-in details for that day
- had to switch to paper because webpage either timed out or showed an error screen, in my group only 2 or 3 completed it online.

ii. Pupil proximity:

- computers were really close together, the room was only half full and everyone could have seen everyone else's screens if they wanted to
- classroom set-up was not ideal. Pupils were seated in five rows of long table, close to each other – this made it difficult for them to fill the questionnaire in privately, as well as ask any questions discretely if they were in the middle of the row
- small class groups instead of large hall with paper copies appeared to work best for ensuring silence and ensuring instructions understood.

iii. Teacher involvement:

- teacher motivation/support for project made a difference to data collection
- issue with those who decline to take part – teachers were unsure how to handle this, with some wanting us to force them to do it
- had to ask the teacher to stay at the top of the room; although she was helpful at the initial demographic stage of the questionnaire (e.g. parents' education, etc.), as the questions went on pupils were getting embarrassed and were afraid to raise their hands in case she came over and not me
- contact teacher and another two teaching assistants were looking over pupils' shoulders throughout (I assume these pupils had reading difficulties and they were helping them with the question)
- chocolate/sweets well received – one school had issue with handing out chocolate products.

iv. Timing:

- we had to wait 30 minutes
- needed some more time in schools to properly explain process, etc.

(B) Pupil issues

i. Confusion:

- had to explain the section asking about the factors influencing decision to have/not have sex
- contraception definition
- problems with difference between penetrative sex and sexual encounter
- found Likert scales example sheet confusing
- misunderstanding of men's roles – girls did not think/know if they should complete it
- did not understand the term 'contraception'
- what does financially mean?
- what does resist peer pressure mean?
- do you have to do the word search?
- what does intimacy mean?
- I have had a sip of alcohol but not gone out drinking, does that count?
- some pupils were confused over whether or not 'contraception' and 'contraceptive' were the same thing, and one pupil asked whether this just included condoms, or other contraceptive methods too
- words that people asked for clarification on: seldom, financially, intimacy, somewhat, sexual advance.

ii. Confidentiality and legal issues:

- whether they could be arrested if they said they'd had sex
- whether anyone would be told their answers (it seems like they really need the confidential stuff drilled into them)
- why do you need to know my post code?
- what if I write a fake post code?
- pupils were really confused about confidentiality – then why is my name/barcode on this, this is not confidential.

iii. Family circumstances

- some pupils did not live with/were not in contact with one or both of their parents – they found some questions difficult to answer
- how to judge how financially well off their family was (Q10)
- many did not know the highest level of education their parents had completed (Q127 + Q13)
- some pupils did not know a lot about their parents' attitudes, and found it hard to judge these
- lots of students did not understand the question about parents' education level or income.

(C) Researcher issues

i. Challenging behaviour:

- persistent talking to each other and looking at each other's questionnaires
- in the second school I visited the teachers made me aware that I was going to be working with a lower reading class who were known to have challenging behaviour. This made it very difficult to enforce exam conditions or keep the answers of the pupils private. They were shouting their answers across the room and looking at each other's questionnaires, which was impossible to stop. It may have been useful to have spaced them out more
- four young people in my group did not have a questionnaire pack because their parents had opted them out. Three of these young people were unaware that they were not to be included and when I asked if they would have liked to participate and complete the questionnaire each said yes they would
- where researchers are in different rooms, spread out over a large building, everyone should have a contact number for everyone else, and keep their mobile phone on.

ii. Additional support:

- for one pupil I had to read the second half of the questionnaire and explain what each question/ answer was
- one student really struggled and simply did not understand the questions; I tried to help but she got really embarrassed and eventually ran out of time and had to get a bus.

Appendix 13 Pupil comments (post trial)

1. If you had not had sexual experience, flicking past questions made it obvious to other peers that you hadn't.
2. Weren't very many answers for people who haven't had sex. It was also obvious to everyone who hasn't had sex, who was taking part as they had to skip loads of pages, making noise and were done quicker.
3. Make it sound less complicated.
4. Less sex questions, also add Mr Krabs to the SpongeBob word search.
5. More questions about something other than contraception.
6. More alcohol and drugs questions.
7. Rethink how questions are asked. Some questions are hard to understand.
8. Word things better.
9. Don't be as forward with the questions.
10. More questions, less personal.
11. Have a lot of variety of questions.
12. Only make us do the questionnaire once.
13. Make the questionnaire shorter.
14. I wouldn't like to do anything else about things like that because I don't like sharing my details with other people.
15. Make one just for boys and a different one for girls.
16. Couple of the questions' structures.
17. Change some questions so they are not as personal or some about other people that you may know.
18. Shorten the length of the questionnaire.
19. Fewer multiple choice questions so people can give their own opinion.
20. Reduce questionnaire size to core questions so it is easier to finish in the period.
21. Fewer questions because a lot of them are irrelevant for people who don't want to have sex at a young age.
22. Questions for those with partners and those without.
23. Instead of saying 'would you ... if under the influence of drink/drugs'. Give an option like 'you wouldn't be in this situation'.
24. In some questions the 'not sure' option wasn't available so add that in.
25. Put people further away from each other, make it more confidential.
26. More sweets.
27. Greater range of questions, in particular for those who do not plan on having sexual relations until they are older. Change the wording on questions as they made me feel like I should have had these experiences before.
28. Have more questions for people who have not taken drugs or had sexual intercourse.
29. Remove the option 'hasn't happened' in some questions.
30. Space people out more.
31. More inclusive questions – questions are mostly heterosexual and gendered (e.g. Question 20 'talking with partner about avoiding pregnancy').
32. Change up questions a bit as it gets very boring doing the same thing three times.
33. Take in that people are Christians, etc., and want to wait till they are older and won't drink and do drugs most likely.
34. Take into account people's religious beliefs.
35. Spread out the tests more.
36. Tell us why we are doing the questionnaire.
37. One questionnaire as all of them were very similar.
38. Goodie bag filled with contraception.
39. Just keep doing what you're doing.

40. Make it less formal, include some funny images or funny stories to make the person completing the questionnaire more comfortable and at ease.
41. Educate us more on the outcomes of an UTP so we have a better understanding.
42. More interactive.
43. Ask what the school says on UTP and how the school teaches students to avoid it.
44. Ask, what is your opinion on teenage pregnancy, what are others' opinions (e.g. peers, parents).
What is your opinion of people who are sexually active at a young age?
45. Fewer multiple choice questions so people can give their own opinion.
46. Make some questions easier to understand.
47. Talk more about sexual encounters.
48. There should be more emphasis on the drugs and alcohol.
49. Not involving a certain number for someone. Not asking for address and financial questions.
50. Not such personal questions.
51. Have an 'I don't do drugs, drink, never had sex' tick box.

Categories and frequencies of responses

TABLE 54 Categories and frequencies of responses

Category	Question and response	Frequency (number)
Good things		
1	It was informative/interesting/relevant/makes you think	106
2	Missing class	81
3	Sweets/chocolates	71
4	Easy to complete/understand as explanations were given	63
5	Confidential/comfortable/opportunity to tell the truth	25
6	The researchers were helpful/nice	21
7	Puzzle at the end	7
8	Helps with research	4
Bad things		
1	Quite long/repetitive/boring	112
2	Some personal/awkward/embarrassing/uncomfortable questions	88
3	Some questions do not apply/irrelevant to some people (e.g. age/experience/different genders or sexualities)	26
4	Did not understand: confusing terms/questions/structure	23
5	Missing class/sport training	20
6	Confidentiality questioned: postcode/other pupils nearby – privacy	15
7	Have to read/write/think/need more time	3
8	Awkward when parents get involved	2
9	No prizes for crosswords	2

A decorative graphic consisting of numerous thin, parallel green lines that curve from the left side of the page towards the right, creating a sense of movement and flow.

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